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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

TRIPLE-S SALUD, INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

Case No.

COMPLAINT AND DEMAND FOR JURY TRIAL

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Plaintiff Triple-S Salud, Inc. ("Plaintiff") brings this civil action against Defendant Teva Pharmaceuticals USA, Inc. ("Teva" or "Defendant") under U.S. antitrust laws and the laws of various states. Plaintiff alleges as follows:

INTRODUCTION

1. Since 1981, more than 35 million people worldwide and 700,000 people in the U.S. have died from Human Immunodeficiency Virus ("HIV") infection. Despite the advent of numerous drugs over the past twenty years, the disease continues to affect millions of Americans. As of 2017, more than 1.1 million people in the U.S. were living with HIV and nearly 40,000 new patients are diagnosed with the disease each year.

2. "Gilead" (Gilead Sciences, Inc., Gilead Holdings, LLC, Gilead Sciences, LLC (f/k/a Bristol-Myers Squibb & Gilead Sciences, LLC), and Gilead Sciences Ireland UC (f/k/a Gilead Sciences Limited)) dominates the market for antiretroviral drugs, which are essential to effective HIV treatment. It manufactures three of the four best-selling HIV drugs on the market, as well as many other drugs that are used in HIV combination antiretroviral therapy ("cART"). Presently, more than 80% of U.S. patients starting an HIV drug treatment regimen take one or more of Gilead's products every day.

3. Several of Gilead's HIV medications cost less than $10 to produce; yet for nearly 20 years, Gilead has charged health plans like Plaintiff thousands of dollars for a 30-day supply. With yearly sales in the U.S. exceeding $13 billion, Gilead has extracted enormous profits from its HIV drugs.

4. Gilead's ability to sustain supracompetitive profits in its multi-billion-dollar HIV treatment franchise has been engineered through a comprehensive, illegal scheme to blockade competition. Beginning in 2004, Gilead entered into a series of anticompetitive agreements with competing cART drug makers to:

- Create branded combination drugs, with express bans on using generic components to create competitive drugs even after patents on the combination drugs expired; and
- Delay market entry by competing generic manufacturers for years beyond the date that Gilead's patents would have been invalidated, in exchange for protecting the generic manufacturers from competition at the point of delayed entry.

5. All of these anticompetitive agreements and actions combined to insulate Teva's and Gilead's product portfolio from the drastic price erosion that would have occurred with effective competition, and resulted in billions of dollars in annual excess profits that accrued (and continue to accrue) to Gilead and Teva.

6. As further explained below, Teva's anticompetitive schemes with Gilead involved unlawful contracts, combinations and restraints of trade in the markets for cART regimen drugs and unlawful monopolization in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. Sections 1 and 2, and various states' laws.

7. As a result of Teva's anticompetitive conduct with Gilead, Plaintiff paid more for cART regimen drugs than it otherwise would have paid in the absence of Teva's unlawful conduct with Gilead and has sustained, and continues to sustain, damages in the form of overcharges paid for its members' prescriptions of cART regimen drugs.

8. Plaintiff seeks redress for the economic harm it has sustained as a result of Teva's violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. Sections 1 and 2, and various states' laws. Plaintiff also seeks injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. Section 26.

NATURE OF THE ACTION

9. Combination antiretroviral therapy regimen drugs are commonly used to treat patients with HIV. HIV can result in Acquired Immunodeficiency Syndrome ("AIDS") and death. Modern antiretroviral cART drug regimens comprise a combination or "cocktail" of drugs, most often consisting of two nucleotide/nucleoside analogue reverse transcriptase inhibitors ("NRTIs") taken with at least one antiretroviral drug of another class, such as an integrase inhibitor, commonly referred to as "third agents." Tenofovir, one of the principal NRTIs used in cART regimens, was discovered more than 30 years ago and has long since lost any patent protection.

10. In 2001, Gilead began marketing tenofovir disoproxil ("TDF") as Viread. TDF is a "prodrug" of tenofovir, meaning that TDF has slight alterations from tenofovir, and, in the

body, TDF metabolizes into tenofovir. Considering these slight alterations, Gilead's patents on TDF were weak and vulnerable to attack by generic competitors.

11. In 2003 and 2004, Gilead began marketing emtricitabine (commonly, "FTC") as Emtriva. It then launched a fixed-dose combination ("FDC") drug comprised of TDF and FTC called Truvada. Like TDF, FTC became a principal NRTI, and the two together were described as the "[r]ecommended NRTI backbone for most initial [cART] regimens."[1] However, also like TDF, Gilead's patent protection on FTC was weak, as Gilead obtained its rights to FTC from others who had publicly disclosed FTC over ten years earlier.

12. In December 2004, Gilead entered into an agreement with "BMS" (Bristol-Myers Squibb Company, and E.R. Squibb & Sons, L.L.C.) to combine Gilead's Truvada (TDF/FTC) and BMS's Sustiva (efavirenz, "EFV") into an FDC named Atripla (TDF/FTC/EFV). At the time, Gilead expected imminent challenges to its patents covering Truvada and sought to combine Truvada with Sustiva so that the resulting combination would be protected by BMS's patents. Gilead and BMS aggressively promoted Atripla and induced physicians and patients to switch their prescriptions from other TDF-based drugs to Atripla, knowing that those physicians and patients would be reluctant to switch back to their earlier, standalone drugs when generic versions of those drugs became available. As a result, Gilead and BMS could continue to charge supracompetitive prices for Atripla even after standalone generic versions of the Atripla components launched.

13. The Gilead-BMS Atripla agreement included a "No-Generics Restraint" clause, which barred both parties from using generic versions of each other's standalone drugs to make partially-generic versions of Atripla, even after the patents on their standalone drugs expired. For example, BMS could not make a combination drug that would compete with Atripla consisting of generic Truvada (TDF/FTC) and Sustiva (EFV).

14. In 2009, Teva Pharmaceuticals USA, Inc. ("Teva") challenged Gilead's TDF patents. Gilead responded by suing Teva and then entering into an unlawful reverse payment

[1] HHS Panel on Antiretroviral Guidelines for Adults and Adolescents (Nov. 13, 2014), https://clinicalinfo.hiv.gov/en/guidelines/archived-guidelines/adult-and-adolescent-guidelines.

settlement agreement with Teva, with the intent and effect of eliminating Teva's patent challenges to Gilead's core group of TDF-based drugs: Viread, Truvada, and Atripla.

15. In February 2013, the day before trial, Gilead and Teva announced a settlement that delayed the introduction of generic Viread by more than 4.5 years until December 15, 2017, only six weeks before Gilead's TDF patents were set to expire. In exchange, Gilead granted Teva six weeks of exclusivity as the only seller of generic Viread — a deal that was worth over $100 million to Teva.

16. Then, in February 2014, the day before closing arguments in a trial concerning Gilead's FTC patents, Gilead and Teva announced another settlement. This one delayed the introduction of generic Truvada and Atripla by more than 6.5 years until September 30, 2020, one year before the expiration of Gilead's patents. In return, Gilead granted Teva six months of exclusivity as the only seller of generic Truvada and Atripla — a deal that was worth more than $1 billion to Teva.

17. In the absence of Teva's unlawful conduct with Gilead, generic versions of cART regimen drugs would have launched years earlier. Competition from TDF-based generics would have driven prices down to competitive levels.

18. Plaintiff has sustained, and continues to sustain, injuries to its business and property as a result of Teva's conduct with Gilead.

JURISDICTION AND VENUE

19. This Court has subject-matter jurisdiction over this action pursuant to 15 U.S.C. §§ 15 and 26, and 28 U.S.C. §§ 1331 and 1337, as Plaintiff asserts claims for violations of Sections 1 and Section 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and seeks injunctive relief under Section 4 and Section 16 of the Clayton Act, 15 U.S.C. § 15(a) and § 26. This Court has subject-matter jurisdiction over Plaintiff's state law claims under 28 U.S.C. § 1367 because its state law claims are so related as to form part of the same case or controversy as its federal claims. Exercising supplemental jurisdiction over Plaintiff's state law claims will avoid unnecessary duplication and multiplicity of actions and, therefore, promotes judicial economy, fairness, and convenience.

20. This court would also separately have jurisdiction over these claims under 28 U.S.C. § 1332(a), as the amount in controversy exceeds $75,000.00 and involves diversity of citizenship.

21. Venue in this District is proper pursuant to 15 U.S.C. §§ 15 and 22, 28 U.S.C. §§ 1391(b)-(d), and 28 U.S.C. § 1407. At all relevant times, Defendant transacted business within this District, carried out interstate trade and commerce in substantial part in this District, and/or have an agent and/or can be found in this District. Defendant sold and distributed the relevant drugs in a continuous and interrupted flow of interstate commerce, which included sales of relevant HIV cART drugs in the U.S. (including in this District). Defendant's conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce in the U.S. (including in this District).

22. This Court has personal jurisdiction over the Defendant because the Defendant transacted business throughout the U.S. (including in this District); sold and distributed cART market drugs, including one or more of the relevant drugs, throughout the U.S. (including in this District); engaged in an unlawful conspiracy to restrain trade for cART market drugs, including one or more of the relevant drugs, that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the U.S. (including in this District); entered into agreements for the development and manufacture of cART market drugs, including the relevant drugs in the U.S. (including in this District); has registered agents in the U.S. (including in this District); may be found in the U.S. (including in this District); and is otherwise subject to the service of process provisions of 15 U.S.C. § 22. Teva's co-conspirator Gilead also has a principal place of business in this District.

PARTIES

23. Plaintiff Triple-S Salud, Inc. is a Puerto Rico corporation. Triple-S Salud, Inc. has its principal place of business in San Juan, Puerto Rico, and is an independent licensee of the Blue Cross and Blue Shield Association.

24. Triple-S Salud, Inc., through itself and its subsidiaries (all of whom have assigned claims to Triple-S Salud, Inc. in this action) provides a full spectrum of health care plans and

services, including prescription drug benefits, to over one million members. At all times relevant to this Complaint, when any of Triple-S Salud, Inc.'s members filled a prescription of HIV cART drugs at a third-party pharmacy, Triple-S Salud, Inc. has paid a large share of the cost of those drugs. For instance, over the relevant time period, Triple-S Salud, Inc. paid a substantial amount to third-party pharmacies for HIV cART drugs dispensed to its members.

25. Triple-S Salud, Inc. is also authorized to bring claims for purchases it makes on behalf of services it offers to other health plans. More specifically, Triple-S Salud, Inc. offers "Administrative Services Only" ("ASO") services to self-funded health plans. Under these ASO agreements, Triple-S Salud, Inc. serves as a third-party administrator to self-funded health plans for purposes of claims processing and other services.

26. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation with a principal place of business at 400 Interpace Parkway #3, Parsippany, New Jersey 07054.

CO-CONSPIRATORS

27. Gilead Sciences, Inc. is a Delaware corporation with a principal place of business at 333 Lakeside Drive, Foster City, California 94404.

28. Gilead Holdings, LLC is a Delaware limited liability company with a principal place of business at 333 Lakeside Drive, Foster City, California 94404. Gilead Holdings, LLC is a wholly-owned subsidiary of Gilead Sciences, Inc.

29. Gilead Sciences, LLC (f/k/a Bristol-Myers Squibb & Gilead Sciences, LLC) is a Delaware limited liability company with a principal place of business at 333 Lakeside Drive, Foster City, California 94404. Gilead Sciences, LLC is now a wholly owned subsidiary of Gilead Sciences, Inc.

30. Gilead Sciences Ireland UC (f/k/a Gilead Sciences Limited) is an Irish unlimited liability company with a principal place of business at IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland. Gilead Sciences Ireland UC is a wholly-owned subsidiary of Gilead Sciences, Inc.

REGULATORY BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand-Name Drugs.

31. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers seeking to market a pharmaceutical product must obtain FDA approval by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b). The products based on these NDAs are generally referred to as "brand-name drugs" or "branded drugs."

32. When the FDA approves an NDA, the drug product is listed in an FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." The FDA lists in the Orange Book any patents which, according to the information supplied to the FDA by the brand manufacturer: (1) claim the approved drug or its approved uses; and (2) the manufacturer believes could reasonably be asserted against another manufacturer that makes, uses, or sells a generic version of the brand drug. 21 U.S.C. § 355(b)(1). A manufacturer must submit this patent information within thirty days of NDA approval, or, for any later-issued patent, within thirty days of issuance of the patent. 21 U.S.C. § 355(c)(2).

33. The FDA relies completely on a brand manufacturer's truthfulness and representations in submitting patents to be listed, as it does not have the resources or authority to verify the validity or relevance of the manufacturer's patents. Therefore, in listing patents in the Orange Book, the FDA merely performs a ministerial act.

34. A drug that receives NDA approval may be entitled to regulatory exclusivity for a limited period of time — in other words, the FDA cannot approve any generic drug applications during this period.

B. The Hatch-Waxman Amendments.

35. When a branded drug's regulatory exclusivity is about to expire, a manufacturer seeking approval to sell a generic version of a branded drug may file an Abbreviated New Drug

Application ("ANDA") that demonstrates that a generic version of the drug is essentially the same as the branded version: i.e., has the same active ingredients, dosage form, safety, strength, absorption, route of administration, quality, performance characteristics, and intended use. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

36. An ANDA relies on the scientific findings of safety and effectiveness included in a brand manufacturer's original NDA and must further show that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns an "AB" rating to a generic drug that is therapeutically equivalent to a brand-name counterpart, indicating the drugs may be substituted for one another. 21 U.S.C. § 355(j)(8)(B).

37. Congress had two goals in enacting the Hatch-Waxman Amendments. First, it sought to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Second, it sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

38. To incentivize the development of new drugs, the Hatch-Waxman Amendments created a 5-year period of new chemical entity ("NCE") exclusivity. Following the approval of an NDA for a drug that has not been approved in any other application, no ANDA may be submitted for that drug for 5 years (or 4 years if the ANDA contains a paragraph IV certification, as discussed in the next section). *See* 21 U.S.C. § 355(j)(5)(F)(ii).

39. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009 total prescription drug revenue had soared to $300 billion.

C. Paragraph IV Certifications.

40. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug will not infringe any valid patents listed in the Orange Book. A generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA;

ii. that the patent for the brand drug has expired;

iii. that the patent for the brand drug will expire on a particular date and the generic manufacturer does not seek to market its generic product before that date; or

iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "paragraph IV certification").

41. If a generic manufacturer files a paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA by suing the ANDA applicant for patent infringement. If the brand manufacturer sues the generic filer within forty-five days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Before then, the FDA may grant only a "tentative approval" to an ANDA if it determines that the ANDA would otherwise be ready for final approval.

42. As an incentive to spur generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a paragraph IV certification typically gets 180 days of market exclusivity (unless a forfeiture event occurs, as discussed below). This means that the first approved generic is the only available generic for at least six months, which effectively creates a duopoly between the brand company and the first-filing generic during this period. This 180-day exclusivity period is extremely valuable to generic companies. When there is only one generic on the market, the generic price is lower than the branded price, but much higher than the price after multiple generic competitors enter the market.

43. Generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market. In a 2019 report, the FDA stated that products with a single generic producer yield a generic average manufacturer price that is 39% lower than the brand before generic competition; with two competitors, generic prices are 54% lower than the brand before generic competition; and with four competitors, generic prices are 79% less than the brand before generic competition.[2] Being able to sell at the higher duopoly price for six months may be worth hundreds of millions of dollars.

44. Brand manufacturers can "game the system" by listing patents in the Orange Book (even if such patents are not eligible for listing) and suing any generic competitor that files an ANDA with a paragraph IV certification (even if the generic competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30 months. That brand manufacturers sue generic manufacturers under Hatch-Waxman simply to delay generic competition — as opposed to enforcing a valid patent that is actually infringed by the generic — is demonstrated by the fact that generic manufacturers prevail 73% of the time by either obtaining a favorable judgment or the brand manufacturer's voluntary dismissal.

45. The first generic applicant can help the brand manufacturer "game the system" by delaying not only its own market entry but also the market entry of all other generic manufacturers. By agreeing not to begin marketing its generic drug, the first generic applicant delays the start of the 180-day period of generic market exclusivity. This tactic is called exclusivity "parking." It creates a bottleneck because later generic applicants cannot launch until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

46. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") in order to make it more difficult for brand and generic manufacturers to conspire to delay the start of the first filer's 180-day period of

[2] U.S. Food & Drug Administration, Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices, at 2-3 (Dec. 2019), https://www.fda.gov/media/133509/download.

generic market exclusivity. Specifically, the law now provides six mechanisms by which first ANDA filers may forfeit their exclusivity rights, thus allowing second (or later) filers to enter the market before, or at the same time as, first filers.

47. First, under the "failure to obtain tentative approval" provision, forfeiture occurs if the first ANDA applicant fails to obtain tentative approval from the FDA within 30 months of filing a substantially complete ANDA, unless the failure is caused by either a change in or review of the approval requirements. 21 U.S.C.§ 505(j)(5)(D)(i)(IV).

48. Second, under the "failure to market" provision, forfeiture occurs if the first ANDA applicant fails to timely market its generic drug. 21 U.S.C. § 505(j)(5)(D)(i)(I). Forfeiture occurs if the ANDA applicant fails to market its drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that qualified the first applicant for exclusivity (*i.e.*, as to each patent for which the first applicant submitted a paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity, unenforceability, or non-infringement; (ii) a settlement order entering final judgment that includes a finding that the patent is invalid, unenforceable, or not infringed; or (iii) the NDA holder delists the patent from the Orange Book.

49. In addition, a first filer may forfeit its exclusivity rights by (1) withdrawing its ANDA, (2) withdrawing its paragraph IV certifications, or (3) entering into an agreement with another generic, the brand drug application holder, or the patent owner that the Federal Trade Commission decides violates antitrust laws. Finally, first filers may forfeit their exclusivity rights upon expiration of all patents with which exclusivity is associated. *See* 21 U.S.C. § 355(j)(5)(D).

50. Despite these legal reforms, however, brand manufacturers and first-filing generics can structure their settlements to skirt these forfeiture provisions. For example, brand manufacturers can convince generic manufacturers to settle before the patents are held invalid, unenforceable, or not infringed. The brand manufacturer prolongs its monopoly and the generic manufacturer keeps its 180-day exclusivity. When that happens, in order to trigger forfeiture and gain access to the market, subsequent ANDA applicants (with no 180-day exclusivity to entice

them) must obtain a judgment that all patents for which the first filing generic company filed paragraph IV certifications are invalid, unenforceable, or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action concerning patents that the brand manufacturer did not assert against it in a paragraph IV litigation.

51. In addition, brand and generic manufacturers can structure their settlements to provide the generic with 180 days of *de facto* exclusivity even when it is likely that the generic has forfeited that exclusivity under one of the applicable MMA forfeiture provisions, *e.g.*, the failure to obtain tentative approval within 30 months of submitting a substantially complete ANDA. The brand can provide such exclusivity by agreeing not to license any other generic to enter the market any earlier than six months after the generic that has forfeited exclusivity has entered. Unless a subsequent generic is itself able to overcome applicable patent and regulatory exclusivities, such an agreement effectively restores the first generic filer's lost statutory exclusivity. This results in a windfall to the generic manufacturer and a subversion of the regulatory scheme. Because the FDA will not typically make a formal 180-day exclusivity determination until another generic applicant has received final approval and is ready to launch, settlements that confer *de facto* exclusivity — even where *de jure* exclusivity has been forfeited under the MMA — dissuade subsequent generic applicants from trying to obtain a court judgment of invalidity and/or infringement that would trigger the start of the 180-day period. And, because the lion's share of the generic revenues will perceivably go to the first filer, subsequent filers have less incentive to litigate to judgment.

D. The Benefits of Generic Drugs.

52. Generic versions of branded drugs contain the same active ingredient and are determined by the FDA to be just as safe and effective as their branded counterparts. The only material difference between generic and branded drugs is their price: generics are usually at least 25% less expensive than their branded counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission estimates that about

one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the price of the branded product.[3] As a result, competition from generic drugs is viewed by brand-name drug companies such as Gilead as a grave threat to their bottom lines.

53. Due to the price differentials between branded and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists liberally and substantially substitute for the generic version when presented with a prescription for the brand-name counterpart. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise by writing "dispense as written" or similar language on the prescription).

54. There is an incentive to choose the less expensive generic equivalent in every link in the prescription drug chain. Pharmaceutical wholesalers and retailers pay lower prices to acquire generic drugs than to acquire the corresponding brand-name drug. Health insurers, like Plaintiff, and patients also benefit from the lower prices that result from generic competition.

55. Until a generic version of a branded drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the branded drug, and therefore, the brand manufacturer can continue to charge supracompetitive prices without losing substantial sales. As a result, brand manufacturers, who are well aware of generics' rapid erosion of their branded drug sales, have a strong incentive to delay the introduction of generic competition into the market, including through tactics such as those alleged here. Moreover, inhibiting generic competition is also harmful to innovation, as brand manufacturers are incentivized to delay generic competition for existing products, instead of innovating better products in a procompetitive manner.

[3] Federal Trade Commission, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, at 8 (Jan. 2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

E. The Impact of Authorized Generics.

56. The 180-day marketing exclusivity to which first filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day exclusivity period. Such a generic is called an "authorized generic" and is chemically identical to the branded drug, but is sold as a generic product through either the brand manufacturer's subsidiary (if it has one) or through a third-party generic manufacturer. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the first filer's revenue, and substantially reduces drug prices for consumers.

57. In its study, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011), the Federal Trade Commission found that authorized generics capture a significant portion of sales and reduce the first filer generic's revenues by approximately 50% on average during the 180-day exclusivity period.[4] The first-filing generic makes significantly less money when it faces competition from an authorized generic because (1) the authorized generic takes a large share of unit sales away from the first filer; and (2) the presence of an additional generic in the market causes prices to decrease.

58. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, consumers and other drug purchasers such as Plaintiff benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

59. As a practical matter, authorized generics are the only means by which brand manufacturers engage in price competition with manufacturers of AB-rated generic drugs. Brand manufacturers generally do not reduce the price of their branded drugs in response to the entry of AB-rated generics. Instead, they either raise the price to extract higher prices from the small number of "brand-loyal" patients or, more typically, they continue to raise the price of the

[4] Federal Trade Commission, Authorized Generic Drugs: Short-term Effects and Long-Term Impact, at 139 (Aug. 2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

branded drugs at the same intervals and at the same rate at which they raised the price of the drugs prior to generic entry.

60. Given the significant negative impact of an authorized generic on the first-filing generic's revenues, and the absence of any other form of price competition from the branded manufacturer, a brand manufacturer's agreement not to launch an authorized generic has tremendous economic value to a generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first filer to delay entering the market. Such agreements deprive drug purchasers such as Plaintiff of the lower prices resulting from two forms of competition. During the initial period of delay agreed to by the ANDA filer, they effectively eliminate all competition from AB-rated generic products and allow the brand manufacturer to preserve its monopoly. And, during the period in which the branded company has agreed not to sell an authorized generic, they eliminate competition between the ANDA filer's generic and the authorized generic, giving the ANDA filer a monopoly on generic sales.

61. As a means of compensating first-filing generic manufacturers, brand manufacturers prefer No-Authorized Generics agreements ("No-AG agreements") to cash payments because, in the case of No-AG agreements, a portion of the compensation is paid by purchasers of the drug in the form of higher generic drug prices. The generic manufacturer receives not only the profits that the brand manufacturer would have made by launching an authorized generic in competition with the ANDA filer's product, but also the higher prices that result from the absence of that competition. Thus, the payment to the generic manufacturer is shared between the brand manufacturer and the generic manufacturer's customers.

ANTICOMPETITIVE CONDUCT

A. The Origin of Gilead's cART Franchise.

62. In 2001, Gilead began marketing and selling Viread (TDF, 300 mg), and in 2003, it began marketing and selling Emtriva (FTC, 200 mg). Viread and Emtriva are both NRTIs indicated for treating HIV-1 infection in adults and certain pediatric patients. These NRTIs quickly became two of Gilead's best-selling products, generating billions of dollars in sales per year. However, Gilead knew the patents covering both of these drugs were weak and vulnerable.

63. As Gilead's new chemical entity ("NCE") exclusivity on Viread (TDF) was nearing expiration, Gilead needed a way to protect its monopoly. Instead of innovating, Gilead made Truvada (TDF/FTC), a single pill that combines Viread (TDF, 300 mg) and Emtriva (FTC, 200 mg) — at the same doses as the standalone versions of each drug.

64. Gilead submitted its Truvada NDA as a "priority" submission of "Type 4 — New Combination" in March 2004, and it was approved by the FDA less than five months later on August 2, 2004 for use in combination antiretroviral treatments for HIV-1 infection in adults.

65. Unlike typical NDA submissions, which require lengthy and costly clinical trials and research, Gilead's Truvada NDA was approved based on a showing that Truvada (TDF/FTC) was bioequivalent to an administration of its separate components (TDF and FTC). Gilead offered no evidence that Truvada (TDF/FTC) provided a pharmacological benefit over standalone Viread (TDF) plus standalone Emtriva (FTC).

66. Gilead began selling Truvada in August 2004. Truvada quickly became a blockbuster drug and has been one of Gilead's top selling HIV products, historically accounting for approximately one-quarter of its HIV sales and almost 12% of its total sales. Within two years of its launch, Truvada became a billion-dollar earner for Gilead.

67. Moreover, in July 2012, Truvada (TDF/FTC) became the first drug approved for use as a pre-exposure prophylaxis ("PrEP") — one of the most effective ways to prevent HIV infections in HIV-negative individuals. Even now, Truvada is one of only two drugs approved for PrEP — the other being Gilead's Descovy (TAF/FTC).[5] The use of PrEP is a priority for public health, and PrEP medications are indispensable in terms of ending the HIV/AIDS epidemic in the U.S. As a result, "Truvada for PrEP" is now covered in all state Medicaid programs. Reduced pricing of Truvada for PrEP would have greatly benefited efforts to end the public health AIDS/HIV epidemic.

[5] *See* U.S. Food & Drug Administration, FDA Approves Second Drug to Prevent HIV Infection as Part of Ongoing Efforts to End the HIV Epidemic (Oct. 3, 2019), https://www.fda.gov/news-events/press-announcements/fda-approves-second-drugprevent-hiv-infection-part-ongoing-efforts-end-hiv-epidemic.

68. Following the approval of Truvada for PrEP, Truvada sales skyrocketed even further. In 2016, there were 77,120 PrEP users in the U.S. compared to just over 8,000 in 2012. Gilead acknowledges this increase was "primarily due to a higher average net selling price and higher sales volume in the United States, as a result of the increased usage of Truvada for PrEP."[6] Without generic competition in the U.S. market until only recently, Gilead has been able to raise prices year after year, consistently earning in excess of $2 billion annually for Truvada sales.

B. Gilead and BMS Enter into a No-Generics Restraint Agreement Related to Atripla.

69. Truvada was successful, so Gilead knew that it could dominate the market even further by combining its drugs with others and protecting them with anticompetitive agreements.

70. In December 2004, Gilead entered into a product combination agreement with BMS to develop and commercialize Atripla (TDF/FTC/EFV). Atripla was to be a combination of Gilead's Viread (TDF) and Emtriva (FTC), along with BMS's standalone Sustiva (EFV) — a third agent. Gilead and BMS structured their arrangement as a limited liability company named Bristol-Myers Squibb & Gilead Sciences, LLC (n/k/a Gilead Sciences, LLC) headquartered in Foster City, CA. Pursuant to the collaboration agreement between Gilead, BMS and Bristol-Myers Squibb & Gilead Sciences, LLC — Gilead and BMS supplied the company with quantities of their respective drug components for the company to manufacture and sell Atripla from California. In return, the company made payments from California to Gilead and BMS for the supply as well as a percentage of revenue from the net sales of Atripla. Gilead and BMS granted royalty-free sublicenses to the company for the use of the companies' respective technologies and, in return, were granted a license by the company to use intellectual property resulting from the collaboration.

71. The agreement included a No-Generics Restraint provision that expressly prohibited either party from marketing an alternative TDF/FTC/EFV product using a generic version of any of its three components. By ensuring that only one version of Atripla would be

[6] Gilead Sciences, Inc., 2016 Form 10-K Annual Report.

marketed using branded components at inflated prices, Gilead and BMS unreasonably restrained trade and protected their drug from competition.

72. This No-Generics Restraint was neither necessary nor reasonably ancillary to achieving the objective of the product combination agreement. By prohibiting the marketing of generic versions of any of the three components, Gilead and BMS hindered competition and innovation of additional products for consumers.

73. The No-Generics Restraint made no independent economic sense. Absent the restraint, competitors like Gilead and BMS would challenge patents and incorporate generic components or comparable components to produce a competing Atripla FDC as soon as possible. It would be in their individual economic interests to market competing generic-drug-based or comparable-drug-based FDCs as soon as possible.

74. The No-Generics Restraint only benefitted Gilead and BMS by impairing competition. Before they lost patent or regulatory exclusivity, neither Gilead nor BMS received any benefit from the No-Generics Restraint because no generic was available. The No Generics Restraint produced benefits only after the relevant statutory exclusivities expired. Such contractual relief from competition is anticompetitive.

75. Absent the No-Generics Restraint, BMS or a reasonable company in its position would have been motivated to market a competing version of Atripla comprised of generic TDF, generic FTC (once available), and EFV, or alternatively generic TDF, generic 3TC, and EFV, while Gilead sold the original version of Atripla. The price of Atripla would plummet due to competition that should have ensued with the availability of generic TDF.

76. The agreement included a termination provision, but the provision actually discouraged termination. If one of the parties sought to terminate the agreement, the terminating party was required to pay the non-terminating party three years of royalty payments, and the terminating party would then become the sole member of the company. This substantial penalty discouraged either party from terminating the agreement in the event that generic versions of TDF, FTC, and/or EFV became available and discouraged the marketing of a competitive form of Atripla with lower-priced generic components, even after the relevant patents had expired.

Further, if either party terminated the agreement, the other's ability to continue making and selling Atripla would terminate. As a result, even if a generic version of a component drug entered the market, a competitive version of Atripla using that generic component could not come to market. If neither party terminated the agreement, both would continue to be bound by the exclusivity provision and could not make a competing generic-composition-based version of the FDC; if a party terminated, then the other would no longer have access to the terminating party's composition and could no longer make any version of Atripla.

77. Absent Gilead's illegal generic delay agreement with Teva, generic TDF would have become available as early as 2014, and purchasers of Atripla should have benefitted from multiple competitive versions of Atripla. Even when generic TDF finally became available in December of 2017, Atripla purchasers were denied competitive alternatives because Gilead (not BMS) then terminated the joint venture to insulate its generic component from competition. The venture's name changed to Gilead Sciences, LLC, a wholly owned subsidiary of Gilead Sciences, Inc.

78. Gilead and BMS further engaged in an aggressive co-promotional marketing campaign to induce prescription switches from standalone Viread (TDF), Emtriva (FTC), and Sustiva (EFV) (which would soon be facing generic competition) to Atripla, which was insulated from generic competition under the Gilead-BMS agreement.

79. The Gilead-BMS agreement substantially increased Gilead's incentive to move sales and market share from TDF and/or FTC to Atripla. The switched sales resulted in BMS selling significantly more EFV than it would have otherwise. The agreement allowed Gilead and BMS to maintain a monopoly in the Atripla market, generating higher than normal prices for not only Atripla but the individual standalone components as well.

80. Absent Gilead and BMS's agreement to forgo use of generic components in Atripla FDC formulation(s), an unrestrained competitor in BMS's position would have challenged Gilead's patents one year before expiration of NCE exclusivity on July 2, 2008, and could have entered the market as early as January 2011.

81. In 2004, when Gilead and BMS entered into their non-compete agreement, Gilead expected generic competition for TDF and FTC years before the January 2018 (for TDF) and September 2021 (for FTC) expiration of patents listed in the Orange Book. BMS likewise expected generic competition years before the July and August 2018 expiration of the Orange Book-listed patents covering EFV. Gilead and BMS's agreement to combine their branded TDF, FTC, and EFV components into an FDC while agreeing not to market any other Atripla FDC with generic components substantially extended their expected exclusivity, particularly in view of the weakness of the patents covering these components, as discussed below.

82. Atripla (TDF/FTC/EFV) was approved by the FDA on July 12, 2006, roughly two years after Truvada (TDF/FTC), for use alone or in combination antiretroviral treatment of HIV-1 infection in adults. As in the case of Truvada, Gilead was not required to conduct lengthy clinical trials and investigations to support its Atripla NDA, because the three components had previously been tested and proven safe and effective on their own. For approval of its Atripla NDA, Gilead merely had to establish bioequivalence to concurrent administration of the individual components. The FDA approved the Atripla NDA less than three months after its submission.

83. At least part of Atripla's success is due to Gilead and BMS's aggressive marketing efforts. Knowing that the NCE exclusivity on TDF was set to expire in October 2006, and that the NCE exclusivity on FTC was set to expire in July 2008, Gilead and BMS engaged in marketing to induce and/or reward switching prescriptions to Atripla. Gilead and BMS shared these marketing and sales efforts, co-promoting Atripla in the U.S. from July 2006 through at least 2010.

84. Gilead and BMS's No-Generics Restraint agreement and joint promotion of Atripla exploited substantial imperfections in the HIV prescription drug marketplace: (1) that HIV prescription drug sales are "sticky," and (2) that once a doctor switches a patient from one HIV drug to another, s/he is very reluctant to switch the patient back, even if a generic or lower cost product becomes available. Brand manufacturers take advantage of this stickiness by using their robust sales forces to move a prescription base from products facing imminent generic competition to products expecting a longer monopoly. Timing is critical. If the new product

beats the generic version of the old product to the market, it makes as much as 10 times more in sales than it otherwise would have made.

85. Knowing this, Gilead and BMS agreed to join sales forces to co-promote Atripla, employing various marketing schemes to exploit this market defect. Gilead and BMS were able to switch much of the prescription base from Viread (TDF), Emtriva (FTC), and Truvada (TDF/FTC) to more-expensive Atripla (TDF/FTC/EFV), which was insulated from competition under Gilead and BMS's agreement.

86. The marketing campaign was successful. Like Truvada, Atripla became a top earner for Gilead. In 2008 (just two years after its July 2006 launch), Atripla's sales reached approximately $1.6 billion. And in 2010, Atripla's sales surpassed $2.9 billion. Without generic competition in the U.S. market until only recently, Atripla sales have consistently been at or above $1 billion, making Atripla was one of Gilead's best-selling drugs.

C. Gilead Enters into a Pay-for-Delay and No-AG agreement with Teva Related to Viread.

87. Having delayed the market introduction of its safer and more effective TAF products, Gilead next went to work asserting its weak patents and settling with prospective generic competitors to prolong its existing monopoly over TDF products.

88. Viread (TDF) is a prodrug formulation of tenofovir. Prodrugs are pharmacologically inactive compounds that, once administered, undergo a conversion by the body's metabolic processes to become an active pharmacological agent. Prodrugs were not new or novel at the time Gilead obtained its patents. And, the process for converting a compound like tenofovir into the TDF prodrug would have been obvious to a person of ordinary skill in the art.

89. Gilead did not invent tenofovir. Tenofovir was first invented and patented in the 1980s by Czech scientists of the Institute of Organic Chemistry and Biochemistry (part of the Academy of the Sciences of the Czech Republic) and Rega Stichting v.z.w (together, "IOCB/REGA"). The patents covering tenofovir expired long ago.

90. Gilead obtained an exclusive license to manufacture and use TDF from the Czech institutions that invented it. In 1991 and 1992, Gilead entered into agreements with IOCB/REGA

for the exclusive right to manufacture, use and sell Viread in exchange for payment of a percentage of net revenues received "subject to minimum royalty payments."[7] In 2000, in anticipation of Viread's launch, the agreements were amended to provide for a "reduced royalty rate on future sales" of products incorporating tenofovir in return for an up-front payment from Gilead. In 2004, in anticipation of the launches of Truvada and Atripla, Gilead again amended the agreements to include Truvada and "any future fixed-dose combination products that contain the licensed technology." At the same time, the Czech institutions, understanding the need for accessible and affordable medications to end the HIV epidemic, agreed to waive any right to royalty payments for Viread or Truvada in developing countries where products are sold at or near cost.

91. Patents are intended to encourage innovation by offering protection from competition for inventions that are novel, useful, and non-obvious. A 2003 report by the Federal Trade Commission found that the average patent application gets approximately 15-20 hours of review time by the U.S. Patent and Trademark Office's ("Patent Office") assigned examiner.[8] Despite receiving hundreds of thousands of patent applications each year, the Patent Office grants the vast majority of patent applications that it receives.

92. Brand pharmaceutical companies have increasingly engaged in a patent procurement strategy sometimes referred to as "evergreening." "Evergreened" patents include later-filed patents that do not cover the active pharmaceutical ingredient ("API"), but rather claim some ancillary aspect of the drug, such as its delivery method, dosage, minor chemical differences, or release mechanism. These patents — if litigated to judgment — have a high rate of being found invalid or not infringed.

93. Gilead never had any patents on the parent molecule tenofovir. Instead, Gilead's Viread patent portfolio attempted to claim the minor differences reflected in the prodrug as novel. Three of the patents — U.S. Patents Nos. 5,922,695 ("the '695 patent"), 5,977,089 ("the '089 patent"), and 6,043,230 ("the '230 patent") — all derived from the same patent application and

[7] Gilead Sciences, Inc., 2006 Form 10-K Annual Report.
[8] Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (Oct. 2003).

cover the tenofovir disoproxil prodrug. The fourth — 5,935,946 ("the '946 patent") — claimed the fumarate salt of tenofovir disoproxil. The four TDF patents (the '695, '089, '230, and '946 patents) were set to expire on January 25, 2018.

94. Knowing its patents were weak and likely to be invalidated, Gilead filed meritless patent infringement lawsuits against generic challengers of the TDF patents. And Gilead entered into settlement agreements with these challengers before issuance of a final court decision rendering the TDF patents invalid and/or not infringed. Gilead's goal was simple: to delay generic competition for multi-billion-dollar blockbuster drugs as long as possible.

95. Viread's NCE exclusivity expired on October 26, 2006, so any 30-month stay blocking FDA approval of competing generics could have expired as early as April 26, 2009. Therefore, if a generic manufacturer had brought a successful patent challenge (or launched during the pendency of the patent litigation which is sometimes referred to as launching "at risk"), it could have launched a generic version of TDF as early as 2009. Even in the best of circumstances for Gilead, the Orange Book-listed patents for Viread expired by January 2018.

96. On or about July 1, 2009, Teva filed a substantially complete ANDA with the FDA to manufacture and sell a generic formulation of Viread 300 mg tablets. The 300 mg strength of Viread constituted the lion's share of all Viread sales.

97. Teva's ANDA included paragraph IV certifications as to all four patents listed in the Orange Book for TDF — *i.e.*, declarations by the ANDA filer that the patents were invalid, unenforceable, or would not be infringed by the proposed ANDA product.

98. Teva's ANDA, as the first-filed ANDA with paragraph IV certifications for the 300 mg strength, entitled Teva to a lucrative 180-day Hatch-Waxman exclusivity. The vast majority of generic drug profits occur during the 180-day exclusivity period.

99. Gilead initiated Hatch-Waxman patent litigation against Teva by filing a patent infringement lawsuit within the statutory forty-five (45) days. Gilead's filing of the lawsuit triggered a stay preventing the FDA from approving Teva's ANDA until the earlier of either: (1) thirty (30) months had elapsed, or (2) the issuance of a "court decision" finding the patents invalid or not infringed by the ANDA product. *See, e.g.*, 21 U.S.C. §§ 355(c)(3)(C), (j)(5)(B)(iii).

100. The issue presented was a relatively simple obviousness patent analysis. As characterized by Teva in its pretrial pleadings:

> This is a straightforward obviousness case. Three of the patents in suit are directed to a prodrug of the known drug tenofovir (PMPA). The prior art made clear that PMPA is a highly potent anti-HIV drug with poor oral bioavailability. The prior art also disclosed improving PMPA's bioavailability by making a prodrug of it. The particular prodrug disclosed in the prior art, called bis(POM)PMPA, was known to exhibit a manageable but undesirable side effect, whose cause was well understood. ***The person of ordinary skill in the art ("POSA") would therefore have sought an alternative prodrug form*** that would not exhibit that side effect, and would have selected the carbonate prodrug (bis(POC)PMPA) claimed in three of the patents in suit.
>
> The fourth patent relates to a fumarate salt of the bis(POC)PMPA prodrug claimed in the other three patents. As in *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1362 (Fed. Cir. 2007), the prior art disclosed salts of bis(POC)PMPA and identified a motivation to make others, including the fumarate salt. Just as in *Pfizer v. Apotex*, the ***selection of the fumarate salt from the limited number of available pharmaceutically acceptable salts would have been routine.***[9]

101. The court set a bench trial for February 20, 2013. Although Teva received tentative approval of its generic Viread (TDF) ANDA on December 23, 2011, Teva first agreed not to launch at risk until May 1, 2013 (Dkt. 19), and later not until June 1, 2013 (Dkt. 86). Accordingly, Teva could have launched its generic at any point if the court found Gilead's patents invalid, not infringed, or unenforceable, or at least on June 1, 2013, if the court had not issued its judgment by then.

102. An outcome in Teva's favor would have been devastating to Gilead, costing the company billions of dollars in Viread revenues and profits. And Teva had a decided litigation advantage given the weakness of Gilead's patents.

103. The day before trial, February 19, 2013, the parties notified the court they had reached a settlement in principle. Gilead's announcement — issued the same day — stated that Teva would not be allowed to launch a generic version of Viread (TDF) until December 15,

[9] *Gilead Scis., Inc. v. Teva Pharms. USA, Inc.*, No. 1:10-cv-1796, Dkt. No. 112, at 1 (S.D.N.Y. Jan. 28, 2013)) (emphasis added).

2017 — only one and a half months prior to expiration of the TDF patents.[10] Gilead thus bought itself another four and a half years of exclusivity and supracompetitive pricing and profits for Viread. The agreement was finalized in April 2013.

104. Further, the Gilead-Teva settlement did not just regard Viread (TDF). Because TDF is also a component of Truvada (TDF/FTC) and Atripla (TDF/FTC/EFV), the litigation and the settlement addressed all of those products. In other words, Gilead's settlement with Teva extended far beyond the specific TDF patent dispute being litigated, successfully delaying, impairing and/or suppressing potential generic competition for three of its blockbuster HIV drugs in one fell swoop.

105. Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare Modernization Act"), the parties to such patent litigation settlements are required to disclose the terms of the settlements to the Federal Trade Commission and the U.S. Department of Justice ("DOJ"), which are afforded an opportunity to review the terms of such settlements.

106. On or about June 28, 2013, the Federal Trade Commission sent Gilead and Teva a letter objecting to and/or expressing concerns relating to the terms of the settlement agreement, which prompted the parties to request that the court extend the automatic dismissal deadline for the case.[11]

107. As a result, the court ordered a telephonic status conference for August 29, 2013. At the status conference, which was transcribed but originally redacted in certain relevant places, the parties described the Federal Trade Commission's objection to the court in response to the court's question about the "offending provision" of the agreement:

> **THE COURT**: OK. That sounds pretty good. Maybe the upside is I don't have to do a darn thing. All right.
>
> Do you mind my asking what is the offending provision?

[10] Gilead Press Release, Gilead and Teva Reach Settlement Agreement in Viread Patent Litigation (Feb. 19, 2013), https://www.gilead.com/news-and-press/press-room/press-releases/2013/2/gilead-and-teva-reach-settlement-agreement-in-viread-patent-litigation.

[11] *See Gilead v. Teva*, No. 1:10-cv-1796, Dkt. No. 132 (June 28, 2013)).

> **[GILEAD COUNSEL OF RECORD]**: Not at all, your Honor. Just a little bit of background, if I may. The Federal Trade Commission has historically taken issue with settlements between brand companies and generics when those settlements have what are called reverse payments in them where the brand name company pays a sum of money to the generic company, allegedly in exchange for the generic company's agreement to stay off the market longer than the generic company might otherwise have done so.
>
> Not too long ago, your Honor may be aware, the Supreme Court addressed such provisions in a very split court five-three and they found that … such provisions could potentially violate antitrust laws that had to be evaluated under the rule of reason. That has emboldened the [Federal Trade Commission] and has breathed new life into its enforcement efforts.
>
> So now they have reached out in our agreement, and, as I understand it, in some others, to challenge the agreements even though there is no reverse payment provision. No money was to change hands under our agreement. ***There was, however, a provision in which Gilead agreed that if it were to independently and unilaterally determine that it would launch a generic, an authorized generic of its own, it would do so but only if it gave Teva six weeks head start on the Gilead authorized generic. This so-called, in the [Federal Trade Commission's] view, "no authorized generic clause," they have now tried to analogize, in our case and others, to a reverse payment.*** That song, quite frankly, has never had too many folks singing in its choir.[12]

108. Since the August 29, 2013 hearing, numerous courts have agreed with the Federal Trade Commission and found that "no authorized generic" ("No-AG") clauses can and indeed do constitute anticompetitive reverse payments to ANDA filers.

109. Gilead's counsel continued by assuring the court that the parties had simply removed the "no authorized generic" agreement from the settlement:

> **[GILEAD COUNSEL OF RECORD]**: … as of late yesterday afternoon, the parties have determined that they will drop the "offending" provision from the agreement. So we simply now have to prepare and execute a simple amendment to the underlying settlement agreement, send that down to the Federal Trade Commission, and then your Honor will be able to dismiss the case.
>
> …

[12] *Gilead v. Teva*, No. 1:10-cv-1796, Dkt. No. 134, at 4:17-5:21 (Aug. 29, 2013) (emphasis added).

> **[GILEAD COUNSEL OF RECORD]:** … Fortunately, for all concerned, we have resolved it, but we have eliminated the so-called "no AG clause" from the agreement so it is truly inconceivable to us that the [Federal Trade Commission] can have any other complaints …."[13]

110. Thus, counsel for Gilead represented to the court that the No-AG clause was dropped from the patent settlement agreement and no other changes were made to reflect the supposed elimination of the No-AG provision. However, what Gilead and Teva did not disclose was that even though they removed the "No-AG" language from the agreement, they still had an agreement preventing Gilead from launching an AG at the point of Teva's delayed generic entry. That secret agreement did not become apparent until Gilead did ***not*** launch a competing AG when Teva launched its generic on December 15, 2017, and Teva issued a press release announcing its "exclusive" generic Viread launch.[14]

111. Teva's ability to launch its generic without facing competition from Gilead's AG was of great economic benefit to Teva. According to the Federal Trade Commission, in a scenario without a competing authorized generic, the first filer generic immediately gains a substantial share within days of launch, and ultimately will capture up to 90% of the total molecule market. The greater the market share the first filer is able to secure, the greater the long-term advantages, as the first filer usually retains the majority of its exclusive market share even with the presence of multiple generics.

112. Applying these observed market dynamics to this case, Gilead earned annual revenues on Viread of approximately $1 billion before the launch of generic equivalents (or $115 million during the six-week exclusivity period). Teva, as the first filer, claimed at least half of that revenue during the exclusivity period and retained a significantly higher portion of the overall market even beyond the exclusivity period. In such a situation, Teva could expect revenues over $50 million during the six-week exclusivity period without a competing AG.

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[13] *Id*. at 3:22-4:3 & 6:5-9.

[14] Teva Press Release, Teva Announces Exclusive Launch of Generic Viread in the United States (Dec. 15, 2017), https://www.tevapharm.com/news-and-media/latest-news/teva-announces-exclusive-launch-of-generic-viread-in-the-united-states/.

113. Teva's profits would have been significantly lower had Gilead launched a competing AG. According to the Federal Trade Commission, in that event, Teva would obtain only approximately 30% of the market during the six-week exclusivity period.[15] And, Teva's market share would not have increased much higher thereafter.

114. Greater price erosion also cuts into the first filer's revenues. In the above $1 billion drug example, instead of launching at a 10% discount to the brand and making over $50 million in revenues during the six-week exclusivity period, the first filer must launch at a greater discount to compete with the authorized generic. Assuming Teva launched at a 25% discount to the brand and maintained an average 30% market share during the six-week exclusivity period, Teva would only earn revenues of approximately $28 million during the six-week exclusivity period. Gilead's launch of an AG would thus cost Teva over $20 million in revenues during the six-week exclusivity period, and additional hundreds of millions of dollars beyond the exclusivity period as Teva's market share would not recover.

115. Gilead's decision not to launch a competing AG defies rational business logic, as such a move could have offset the expected generic erosion. Moreover, a No-AG agreement runs contrary to Gilead's decision to recognize such profits and launch AGs with respect to multiple other products in its portfolio, including its blockbuster hepatitis C drugs Harvoni and Epclusa, through its subsidiary Asegua Therapeutics.[16] Yet, Gilead never launched a Viread AG.

116. The purpose of the settlement agreement was clear: in exchange for delayed generic entry, Teva would be granted exclusive entry into the market without competition from a Gilead AG. This No-AG agreement was a payment from Gilead to Teva worth substantially more than what Teva could have earned if it had prevailed in the patent litigation and come to market with a generic Viread in competition with Gilead's AG. This reverse payment from

[15] *See, e.g.*, Federal Trade Commission, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact (Aug. 2011).

[16] *See, e.g.*, Gilead Press Release, Gilead Subsidiary to Launch Authorized Generics of Epclusa and Harvoni for the Treatment of Chronic Hepatitis C (Sept. 24, 2018), https://www.gilead.com/news-and-press/press-room/press-releases/2018/9/gilead-subsidiary-to-launch-authorized-generics-of-epclusa-sofosbuvirvelpatasvir-and-harvoni-ledipasvirsofosbuvir-for-the-treatment-of-chronic.

Gilead to Teva exceeded Gilead's anticipated litigation costs to continue pursuing the patent litigation.

117. Gilead also included "most-favored entry" ("MFE") and "most-favored-entry-plus" ("MFEP") provisions in its patent settlements with Teva and other generic manufacturers. MFE clauses benefit first filers but can also be used to incentivize later filers. MFE clauses provide that if any subsequent generic ANDA filer succeeds in entering the market before the agreed-upon date for the first filer, the first filer's entrance will be accelerated and it may enter at the same time as that subsequent filer. A first filer may agree to an MFE in exchange for delayed entry because it knows the MFE will dramatically reduce a second filer's incentive to file an ANDA and challenge the patents. If second filers are aware that they will face immediate competition from a first filer, they are less likely to pursue costly litigation against the brand company. Two entrants inevitably result in reduced market share and lower pricing for both generics.

118. The anticompetitive effects of MFEs may be compounded by increasing the number of generic manufacturers to which the clauses apply. When a second filer is deciding whether to initiate or continue a patent challenge, knowing that the brand manufacturer has already granted an MFE to the first filer and has offered to grant one to the second filer, it could reasonably conclude that the brand manufacturer will also likely grant MFEs to subsequent filers (*i.e.*, the third, fourth, and fifth filers). In these circumstances, the second filer faces the prospect that, even if it expends substantial resources to win the patent case, its "victory" would trigger simultaneous entry into the market by the first filer, possibly an "authorized generic" marketed by the brand manufacturer, and possibly additional generics. Simultaneous entry of multiple manufacturers would quickly push prices down close to marginal cost.

119. MFEP clauses primarily benefit first filers as well. MFEP clauses provide that the brand manufacturer will not grant a license to any second (or subsequent) filer to enter the market until a defined period of time after the first filer enters. Like MFE clauses, MFEP clauses dramatically reduce a later filer's incentive to challenge the patents, because they ensure the first filer's exclusivity for a set period of time. Absent an MFEP, a second filer could use its challenge

to the patents as leverage to negotiate with the brand manufacturer for a license to enter the market before the first filer. This is particularly significant where the first filer has forfeited its 180-day exclusivity by failing to get tentative FDA approval within 30 months. Absent the 180-day exclusivity period, the second filer could enjoy a substantial period of *de facto* exclusivity in the generic sector of the market. The MFEP would eliminate that possibility by ensuring that the second filer could not successfully negotiate for an earlier licensed entry date.

120. By February 2013, the time that Gilead and Teva reached their patent settlement, approximately six other generic drug manufacturers — Lupin, Cipla, Hetero, Aurobindo, Strides Pharma, and Macleods Pharmaceuticals — had filed ANDAs seeking FDA approval to sell generic Viread. The first two of those manufacturers included paragraph IV certifications with respect to the TDF patents, and Gilead had filed suit. Gilead and Teva fully understood that the other four of those six intended to enter the market as soon as possible and would amend their ANDAs to include paragraph IV certifications (as is common in the industry) if it appeared that they had an opportunity for a period of *de facto* exclusivity.

121. In view of this potential competition, Gilead used MFE and MFEP clauses to incentivize Teva to push back its generic entry date. Under the MFE clause, Teva received assurances that no other generic manufacturer would enter the Viread market before Teva. And under the MFEP clause, Teva would be protected from competition from any other generic until the expiration of the TDF patents on January 26, 2018. So Teva received six weeks as the exclusive Viread generic. This reduction in generic competition was enormously valuable to Teva and amounted to a payment. For every week that Teva was on the market as the only generic manufacturer of a standalone Viread (TDF) generic, it could expect to sell all of the TDF units at about 90% of the brand price. Entry of multiple generics would swiftly cause Teva's unit sales and profits per unit sale to decrease. Without MFE and MFEP clauses, Teva faced a substantial risk that it would be stuck on the sidelines while later filers entered the market years in advance and reaped the corresponding gains of being the first generic TDF standalones.

122. Moreover, Teva's competitive advantage was not limited to just the period when no other manufacturer was selling the product. With a certain, single-entrant launch date, Teva

could ramp up its production and negotiate contracts with its customers to effectively flood the distribution channel with product before the second filers entered the market, and lock in high prices with long-term sales contracts. The difference between the single-generic price and the price with multiple generic competitors represented a significant additional cost to purchasers of the drug.

123. The MFE and MFEP clauses also benefitted Gilead. They allowed Gilead to extract an exceedingly favorable entry date — just six weeks before the end of the patent term in mid-January 2018. Such agreements also provided Gilead control over when generic entry would occur and allowed it to further impede competition. Having information as to the timing of generic TDF was essential to Gilead's multi-layered product-hopping schemes and compounded the anticompetitive effects of Gilead's and Teva's concerted plans to delay and suppress generic competition in the markets for these critical HIV drugs. And Gilead used these clauses to reduce the likelihood of substantive patent challenges, by discouraging later filers from litigating. These anticompetitive clauses proved to be effective tools for Gilead to maintain and extend its market dominance.

124. Gilead also included MFE clauses in its settlement agreements with other generic Viread manufacturers. Those MFE clauses persuaded subsequent filers to agree to delay entry until at least six weeks after Teva's entrance into the Viread market, or until January 26, 2018. This meant that Lupin and Cipla, who each litigated the patents for nearly two years, ultimately agreed to delay their generic launch until the patents expired (*i.e.*, they received no advantage over generics that did not litigate). These subsequent filers were made aware of the MFEs in the Gilead/Teva agreement.

125. When agreeing to the delayed December 15, 2017 entry date, Teva knew that: (a) Gilead was willing to include anticompetitive MFEs in settlement agreements with subsequent filers; (b) it was in Gilead's financial interest to include such clauses in agreements with all subsequent filers; (c) the subsequent filers would have known that the Gilead/Teva agreement included an MFE; (d) no subsequent filer after the adoption of the MFEs would have an interest

in incurring the costs of patent litigation to try to enter the market before Teva; and (e) the MFEs' deterrent effect would grow with every additional MFE that Gilead granted in settlement.

126. Just as Gilead intended, the MFEs in the Teva agreement (and others) deterred subsequent ANDA filers and deterred substantive patent challenges. Lupin and Cipla settled their litigations in exchange for no benefit over other ANDA filers. And the other ANDA filers — at least Hetero, Aurobindo, Strides, and Macleods — chose not to amend their ANDAs to include paragraph IV certifications. Absent Gilead's anticompetitive conduct, at least Hetero and Aurobindo would have made such certifications as they made paragraph IV certifications with respect to Truvada.

127. On January 26, 2018, six weeks to the day after Teva entered the market, and the day after the TDF patents expired, five generic manufacturers (Cipla, Hetero, Aurobindo, Strides, and Macleods) received final FDA approval, and four immediately began marketing generic Viread. At least four more ANDAs were finally approved over the next year. Many had received tentative approval years earlier.

128. Viread has been an enormously successful drug for Gilead. After launching in late 2001, Viread quickly became a blockbuster drug. In 2003, Gilead earned $566.5 million in sales and royalty revenues from Viread worldwide. In 2004, that number jumped to $782.9 million. After many years of stable sales of approximately $650-$950 million per year, Viread crossed the $1 billion plateau in 2014. Viread earned $1 billion per year worldwide thereafter through 2017. Teva launched generic Viread on December 15, 2017.

129. In 2017, the year that Teva eventually entered the market, Viread had U.S. sales of $591 million, or about $11 million per week. Generic manufacturers (however many there were) could expect to take at least 80% of Viread's unit sales. As the sole generic on the market, Teva could expect to price its generic at 90% of the brand price and make at least $7.9 million for every week of sales, while as one of seven generics on the market Teva could expect to price its generic at about 20% of the brand price and make a seventh of the total generic sales or about $250,000 for every week of sales. Thus, Gilead and Teva's efforts to forestall generic competition increased Teva's sales by $7.65 million for every week in which it was the only

seller of generic Viread — an increase of $45.9 million over the six weeks secured by the MFEs and MFEPs.

130. During the six weeks secured by the MFEs and MFEPs, Teva was the only seller of generic Viread on the market, and it stuffed the supply chain with its generic Viread product, locking in high prices through long-term sales contracts. Thus, Teva made millions more than it would have absent the MFEs and MFEPs. Absent Gilead and Teva's anticompetitive conduct, Teva and the second filers would have entered the market much sooner than they did. The delay in generic entry protected more than $2 billion in Gilead's Viread branded sales, and the insulation from competition facilitated Gilead's delayed introduction of its TAF products, all at the expense of Plaintiff and others.

D. Gilead and BMS Enter into Pay-for-Delay Agreements Related to Truvada and Atripla.

131. Gilead and Teva's anticompetitive TDF patent settlement established that generic competition to Truvada (TDF/FTC) and Atripla (TDF/FTC/EFV) would be precluded at least until December 2017 — when Teva could launch its generic Viread (TDF). However, litigation regarding the other components of these FDCs pushed their generic entry dates back even further.

132. On or about September 26, 2008, Teva filed substantially complete ANDAs with the FDA to manufacture and sell generic formulations of Truvada and Atripla. For both of these ANDAs, Teva ultimately included paragraph IV certifications as to the four TDF patents (which were litigated alongside Viread, discussed above), the FTC patents, and, for Atripla, the EFV patents. Thus, Teva asserted these patents were invalid, unenforceable, or not infringed by its proposed ANDA products.

133. The Orange Book-listed patents for Truvada and Atripla for the four TDF patents (the '695, '089, '230, and '946 patents) expired on January 25, 2018. The FTC patents expired on May 4, 2021 and September 9, 2021. For Atripla, the patents covering EFV expired July 20, 2018 and August 14, 2018.

134. Like Teva's ANDA for Viread, Teva's ANDAs for Truvada and Atripla were each the first substantially complete applications to be filed, entitling Teva to first filer status for statutory ANDA exclusivity, subject to any forfeiture.

1) BMS and Teva enter into a Pay-for-Delay agreement related to Atripla.

135. BMS contributed EFV for the Gilead-BMS joint development of Atripla (TDF/FTC/EFV). After Teva filed the first Atripla ANDA, BMS filed suit against Teva in March of 2010, accusing it of infringing U.S. Patent Nos. 6,639,071 (the "'071 patent") and 6,939,964 (the "'964 patent"). BMS was initially represented by the same counsel who represented Gilead in its Viread patent infringement litigation against Teva. Merck, Sharp & Dohme Corp., owner of the patents, joined BMS as co-plaintiff. *See Merck, Sharp & Dohme Corp. v. Teva Pharmaceuticals USA, Inc.*, No. 1:10-cv-01851 (S.D.N.Y. filed Mar. 9, 2010). The asserted EFV patents expired on August 14, 2018 and July 20, 2018, respectively.

136. The patents BMS asserted against Teva covered particular crystalline forms of EFV — they did not claim the compound itself, but merely particular ways the molecules may arrange themselves in a crystal. These were weak, and susceptible to invalidity challenges. BMS did not assert the purported composition of matter patent for EFV (which expired in 2013) or the method of use patent for treatment of HIV infection (which expired in 2014). Moreover, BMS specifically chose not to assert the '071 or the '964 patents in an earlier case against Mylan Pharmaceuticals regarding the Sustiva (EFV) standalone drug. There, BMS stated that defendants' Notice Letter "provided a detailed statement of the factual and legal basis for [their] paragraph IV certification regarding" these patents. *Bristol Myers Squibb Co. v. Mylan Pharms. Inc.*, No. 1:09-cv-00651, Dkt. 183, ¶ 20 (D. Del. June 18, 2012). BMS thus believed that Mylan had established — just based on its letter — that its ANDA product did not infringe these patents and/or that they were invalid or unenforceable.

137. In addition to Teva and Mylan, multiple other generics challenged BMS's EFV patents, reflecting the weakness of these patents.

138. Like Gilead, BMS filed the Atripla EFV patent infringement lawsuit without regard to the merits, knowing the EFV patents it asserted were weak and likely to be invalidated and fully anticipating imminent generic competition. BMS knew that there was a substantial probability that it would lose the patent litigation given the weakness of its EFV patents and that it would likely face generic competition years prior to the expiration of its patents.

139. In its Pretrial Memorandum, Teva presented facts that the asserted patents were invalid because they were inherently anticipated and/or obvious. Teva showed that the claimed crystalline structure, "Form I," is inevitably formed by practicing the processes described in either of two different prior art references, rendering the asserted patents invalid. Teva further showed that the "Background of the Invention" sections of the '071 and '964 patents expressly admit that Form I was in the prior art, and state that the novelty of the patents is the use of a different crystallization process (not the discovery of a new crystal form). Yet, the claims of the '071 and '964 cover only the final crystallized forms (i.e., "Form I"), without any reference to the processes used to make them, despite first stating that "[t]he instant invention describes a method for crystallizing [EFV]."

140. On June 5, 2013, less than three weeks before the scheduled trial concerning the EFV patents, the parties had "reached a settlement in principle." The case was officially closed on August 16, 2013.

141. On October 8, 2014, BMS issued a press release announcing the resolution of all its EFV and Atripla patent infringement litigation. It stated: "we believe that loss of exclusivity in the U.S. for efavirenz should not occur until December 2017."[17] Thus, BMS's announcement indicated that it expected to lose exclusivity for EFV on about the same date that Teva had accepted for the launch of its generic TDF.

142. There are now several versions of generic EFV on the market. Mylan, the first filer for EFV, received tentative FDA approval in 2011 and final approval in 2016. However, Mylan did not launch generic EFV until February 1, 2018, just six months before the last-expiring

[17] Bristol-Myers Squibb Press Release, Bristol-Myers Squibb Statement on Sustiva (efavirenz) in the U.S. (Oct. 8, 2014), https://news.bms.com/news/details/2014/Bristol-Myers-Squibb-Statement-on-Sustiva-efavirenz-in-the-US/default.aspx.

asserted EFV patent was set to expire. The terms of the parties' settlement were never fully disclosed.

2) Gilead and Teva enter into a Pay-for-Delay agreement related to Truvada and Atripla.

143. Shortly after the TDF patent settlement and the EFV patent settlement, Gilead entered into a similar anticompetitive settlement agreement with Teva in regard to FTC to further delay the entry of generic Truvada (TDF/FTC) and Atripla (TDF/FTC/EFV). This agreement was a highly effective impediment to generic competition. Until recently, Teva marketed the only generic versions of both drugs. Additional generic manufacturers recently entered both markets, causing prices of generic Truvada and Atripla to plummet.

144. As in the case of Viread, generic erosion of Truvada and Atripla sales would have occurred swiftly. Introduction of generic Truvada and Atripla would have drastically reduced pricing and made these crucial HIV medications more affordable and accessible to those living with HIV.

145. Gilead did not invent FTC. Instead, like for TDF, Gilead obtained rights to it from others. The Orange Book-listed patents for Truvada and Atripla purportedly covering the FTC component include U.S. Patent Nos. 6,642,245 ("the '245 patent") and 6,703,396 ("the '396 patent"). The FTC patents were set to expire on May 4, 2021 and September 9, 2021, respectively.

146. At different times, in an attempt to extend its flagship TDF-based product line, Gilead also listed other patents in the Orange Book for Truvada and Atripla — all of dubious validity. For many of the listed patents, Gilead never asserted them against any prospective generic competitors. Others merely purport to claim the non-inventive pairing of drugs, where such combinations would have been obvious to a skilled artisan. And none of them cover the API, but rather some ancillary aspect of the drug product. As such, these later-listed Orange Book patents were obvious and not novel, and would have likely been found invalid.

147. Like for TDF, Gilead acquired the rights to FTC from the real inventors. In 1990, scientists at Emory University filed the first of a family of patents that disclosed FTC — or, more

precisely, the specific enantiomer (*i.e.*, orientation) of FTC used in Emtriva, Truvada, and Atripla, which is called "(–)-β-FTC." For example, U.S. Patent No. 5,814,639 ("the '639 patent") issued in September 1998 and claimed β-FTC, claimed using β-FTC for HIV treatment, disclosed its two enantiomers (the (+) and (–) enantiomers), and disclosed a technique for separating them.

148. Gilead listed Emory's patents (the '639, '245, and '396 patents), along with Emory's related U.S. Patent No. 5,210,085 ("the '085 patent"), in the Orange Book for Truvada and Atripla. The '245 and '396 patents were the two patents Gilead was asserting against Teva at the time the parties settled their litigation.

149. In April 1996, Triangle Pharmaceuticals, Inc., obtained an exclusive license to purified forms of FTC for use in HIV and HBV indications. Gilead acquired Triangle in January 2003, including the exclusive rights. Upon that acquisition, Gilead rushed standalone Emtriva (FTC) and Truvada (TDF/FTC) to market. The FDA approved standalone Emtriva (FTC) in July 2003, roughly six months after Gilead acquired the license to FTC. In March 2004, less than a year later, Gilead filed its NDA for Truvada (TDF/FTC), which the FDA approved in August 2004 (less than five months after Gilead's initial submission).

150. The NCE exclusivities for FTC as a component of Truvada and Atripla expired on July 2, 2008. As a result, any 30-month stay blocking FDA approval of a competing generic could have expired as early as January 2, 2011. That means that a generic manufacturer bringing a successful patent challenge against Truvada or Atripla could have launched a generic version of Truvada or Atripla as early as 2011. Even in the best of circumstances for Gilead, the Orange Book-listed patents were to expire by their own terms in January of 2018 for TDF and in September of 2021 for FTC.

151. Gilead sued for patent infringement within forty-five (45) days of receiving Teva's paragraph IV certifications. Gilead's filing triggered a stay preventing the FDA from approving Teva's ANDAs for Truvada and Atripla until the earlier of thirty (30) months or the issuance of a court decision finding the patents at issue invalid, unenforceable, or not infringed.

152. Gilead filed suit against Teva on December 12, 2008, alleging its generic Truvada would infringe the '245 and '396 FTC patents. On September 25, 2009, Gilead amended its

patent infringement complaint, adding allegations that Teva's generic Atripla would also infringe these patents.

153. Gilead filed its FTC patent infringement lawsuits without regard to the merits of those cases. It knew that the patents were weak, fully anticipated that generic manufacturer(s) would successfully challenge the patent claims, and expected to face imminent generic competition. When it sued Teva in December of 2008, Gilead knew there was a substantial probability that it would lose the patent infringement litigation because of the weakness of its patents. Gilead's 2008 SEC Form 10-K reported:

> Teva alleges that two of the patents associated with [FTC], owned by Emory University and licensed exclusively to [Gilead], are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of a generic version of Truvada. In December 2008, we filed a lawsuit in U.S. District Court in New York against Teva for infringement of the two [FTC] patents. We cannot predict the ultimate outcome of the action, and we may spend significant resources defending these patents. If we are unsuccessful in the lawsuit, some or all of our original claims in the patents may be narrowed or invalidated, and the patent protection for Truvada in the United States would be shortened to expire in 2017 instead of 2021.[18]

154. In September 2013, the parties filed pretrial memoranda, and the four-day bench trial began on October 8, 2013. It focused on one of Teva's strongest contentions: that the patents were invalid for obviousness-type double patenting because the (–)-enantiomer claimed in the '245 and '396 patents was claimed by the earlier-expiring '639 and '085 patents described above. Teva argued that the specific (–)-β-FTC enantiomer was anticipated or rendered obvious by the earlier-expiring patents, because the earlier patents claimed the FTC compound broadly (without regard to its orientation), and further disclosed its two enantiomers and a separation technique.

155. More specifically, Teva maintained that the asserted FTC patents were invalid and an improper attempt to extend Gilead's monopoly beyond the scope of previously-issued patents. As explained in Teva's Pretrial Memorandum, Gilead was trying to parlay the earlier invention and associated patent rights into additional patents (and exclusivities) for uses that were not novel

[18] Gilead Sciences, Inc., 2008 Form 10-K Annual Report.

or new and would have been obvious to person skilled in the art at the time. The claims disclosed in the earlier FTC patents (the '639 and '085 patents) relating to the discovery of FTC for HIV treatment rendered the later-obtained FTC patents (the '245 and '396 patents) invalid as obvious and/or anticipated:

> What is relevant is that [Gilead et al.] are entitled only to a single patent term for [FTC], irrespective of the value or properties of that drug. Plaintiffs received the complete protection the law allows when they received the '639 and '085 patents, which claim emtricitabine and its only use. [***Gilead et al.***] ***are not entitled to an extra six-year monopoly simply for recycling those patents and again claiming emtricitabine and that use***. Upon the expiration of the '639 and '085 patents, the population that suffers from AIDS is entitled to obtain that drug, and the generic drug industry is entitled to offer it to that population, at a non-monopoly price. That is the promise of the Hatch-Waxman Act, Congress's expression of the public policy that favors the introduction and distribution of generic drugs not protected by valid patents.[19]

156. Teva's anticipation sub-theory gave Teva a clear path to a verdict in its favor. To prevail on the anticipation sub-theory, Teva needed to show that a person of ordinary skill in the art would visualize the (–)-β-FTC enantiomer when presented with the chemical structure of β-FTC, and that such a person could obtain (–)-β-FTC without undue experimentation. The first requirement was undisputedly met (although Gilead argued that this was not dispositive). And Teva conclusively proved the second requirement at trial.

157. On the first element, whether a person of ordinary skill in the art would find (–)-β-FTC obvious based on publicly-available information, the court was deeply skeptical of Gilead's main argument. Gilead did not dispute that a person of ordinary skill in the art would visualize (–)-β-FTC when presented with the chemical structure of β-FTC, but argued that pure (–)-β-FTC was one of an infinite number of potential ratios between (–)-β-FTC and its enantiomer (+)-β-FTC. Therefore, Gilead contended, a person of ordinary skill in the art would envision (–)-β-FTC as just one member of an infinite universe, rather than something readily identified. When Gilead

[19] *Gilead Scis., Inc. v. Teva Pharms. USA, Inc.*, No. 08-cv-10838, Defs' Mem. in Opp. to Pltfs' Pretrial Mem., Dkt. 152, at 1 (S.D.N.Y. Sept. 23, 2013) (emphasis added).

made this argument in its opening statement at trial, the court (which did not challenge any part of Teva's opening statement) said,

> That's just a mathematical proposition, right? I mean if there's billions or millions, hundreds of millions of molecules, then I guess you might have one or two and then the balance all one [*sic*] and then everything in between. It's hard for me to see why that's a compelling argument, but we'll come to that.[20]

158. Gilead's counsel tried to explain further, but the court interrupted again:

> That's a mathematical proposition that basically there is infinity between point A and point B, so there will be an infinite number of stops along that chain. But I don't think — it seems to me that's not really scientific argument that there are an infinite number of ratios that a scientist of ordinary skill in the art would be looking to experiment to see whether a ratio of 49.6 percent was better than a ratio of 49.7 percent, which might be better or worse than 47.2 percent. That just strikes me as illogical.

159. Gilead's counsel tried again, stating that "a person of ordinary skill in the art would not understand what ratio would be the ratio that might make the best compound." But the court remained unconvinced:

> It would seem a person of ordinary skill in the art even in 1990 would look to separate into the pure forms to see what the efficacy of each was. And, presumably, that would be the starting point rather than start at points in the middle and then start, you know, bit by bit going to either end. So maybe in 1990 they weren't that smart, but it seems to me that that's what a person would logically do.

160. Gilead's counsel tried yet again, responding that "one of ordinary skill in the art would have to envisage all of the mixtures at once in his or her head. They would have to be able to envisage the full claim scope in their head, which is not possible for a person to do." The court did not buy it: "All right. I guess we'll see. I'm not convinced, but we'll see."

161. This exchange was a disaster for Gilead because it showed that the court would not agree with Gilead's "infinite mixtures" theory unless trial testimony showed that a person of ordinary skill in the art in 1990 would have been overwhelmed with that infinity of mixtures, rather than simply looking to separate β-FTC into its enantiomers, (–)-β-FTC and (+)-β-FTC.

[20] *Gilead v. Teva*, No. 08-cv-10838, Trial Transcript — Day 1, Dkt. 162 at 42-45 (S.D.N.Y. filed Oct. 21, 2013).

After a full trial, no testimony remotely supported such a proposition. In fact, witnesses for Gilead and Teva both testified that a person of ordinary skill in the art would have readily visualized (–)-β-FTC after seeing the structure of β-FTC, and that separating and testing enantiomers was common practice. The court also admitted evidence that the FDA encouraged scientists to separate and test enantiomers of chiral compounds, and that the inventors of β-FTC separated the enantiomers of analogous drugs at the request of the drug company Glaxo. Had the case gone to judgment, Teva likely would have prevailed on this element of its anticipation sub-theory.

162. On the other element of its anticipation sub-theory — whether a person of skill in the art could obtain (–)-β-FTC without undue experimentation — Teva elicited powerful evidence that put the lie to a narrative Gilead had promoted throughout the case. Before trial, Gilead claimed that real-world experience had shown that separating the enantiomers of β-FTC required a very high amount of time and ingenuity. Gilead's pretrial brief asserted that "the inventors themselves attempted five of those methods [of separation] during their research (all but one of which failed) before settling on enzymatic resolution."[21] But one of the inventors admitted at trial that enzymatic resolution was the first method he tried, and he was able to separate the enantiomers with the very first enzyme he tried, pig liver esterase. This was not just an amazing coincidence; the evidence showed that enzymatic resolution was a commonly used method at the time, and the inventor was sure enough that it would work that in the patent application for β-FTC, he listed it as a method for separation even before trying it.[22] Gilead also claimed before trial that the company BioChem took more than a year to separate the enantiomers of BCH-189, a compound similar to β-FTC. That was incorrect. In fact, a technician at BioChem, who had never before attempted to separate enantiomers, testified that she successfully did so with BCH-

[21] *Gilead v. Teva*, No. 08-cv-10838, Gilead Pretrial Mem., Dkt. 137 at 34 (S.D.N.Y. Sept. 9, 2013).

[22] *Gilead v. Teva*, No. 08-cv-10838, Trial Transcript — Day 2, Dkt. 164 at 300-01 (S.D.N.Y. filed Oct. 21, 2013).

189 in "less than 15 days of laboratory time."[23] Based on the evidence at trial, and the judge's view of Gilead's "infinite mixtures" argument, Gilead was very likely to lose.

163. Gilead's arguments against the obviousness sub-theory fared no better. Here, the parties contested whether in light of the patents for β-FTC and its use, it would be obvious to a person of ordinary skill in the art to try to obtain (–)-β-FTC, and whether doing so would involve undue experimentation. As described above, Teva would have prevailed on the second element, as the inventors of β-FTC obtained (–)-β-FTC on their first try, using well-known methods, and a technician at BioChem did the same with a β-FTC analog in less than 15 days. Gilead claimed, however, that the person of ordinary skill in the art would not have been motivated to obtain (–)-β-FTC for various reasons. This was highly implausible because in 1987, three years before (–)-β-FTC was obtained, the FDA issued guidance stating that enantiomers should be separated and may need to be tested:

> When the NDS [*i.e.*, new drug substance] is asymmetric (e.g., contains one or more chiral centers, or has cis-trans or other types of isomers), the sponsor should ideally (and prior to the submission of an IND [*i.e.*, investigational new drug]) have either separated the various potential stereoisomers of the NDS or synthesized them independently. Physical/chemical information about each stereoisomer should be provided (in detail), or may be requested. Individual stereoisomers may need to be studied for pharmacological and toxicological properties (and/or for safety and efficacy).[24]

(Stereoisomers are molecules that have the same sequence of atoms but differ in their three-dimensional structure. Enantiomers are a type of stereoisomer.) Gilead had no real response to this evidence. Moreover, the evidence at trial showed that the separation and study of enantiomers was a regular practice as early as the 1970s, and the development of single-enantiomer drugs was standard practice in the pharmaceutical industry by 1990. And while Gilead had claimed that a person of ordinary skill in the art would have viewed (+)-β-FTC as the

[23] *Gilead v. Teva*, No. 08-cv-10838, Trial Transcript — Day 2, Dkt. 164 at 377-80 (S.D.N.Y. filed Oct. 21, 2013).

[24] U.S. Food & Drug Administration, Guideline for Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances (Feb. 1987).

more obvious candidate for development (instead of (–)-β-FTC), Gilead's own expert and fact witnesses agreed that such a person would have tested both before rejecting either of them.

164. Other generic manufacturers, well aware of the inherent weaknesses of the FTC patents, similarly challenged the patent protection of Truvada and Atripla. In response, Gilead filed lawsuits against nearly each and every potential generic rival, alleging infringement of its duplicitous and ancillary patent portfolios.

165. Gilead and Teva settled the FTC patent case in February 2014 while awaiting the trial court's decision. Notably, Gilead and Teva's settlement of the FTC patent infringement case came shortly after their settlement in mid-2013 of the TDF patent infringement litigation as to Viread, Truvada and Atripla and shortly before Gilead's July 2014 settlement with Cipla, which resolved patent litigations involving both FTC and TDF patents.

166. Having successfully settled the TDF patent case using MFE and MFEP provisions, Gilead and Teva used the same clauses in the FTC case to guarantee a future date certain for Teva's generic entry for Truvada and Atripla in exchange for assurances to Teva that no generic manufacturer would enter the market prior to Teva.

167. The settlement agreements set a date certain for Teva's initial generic entry and further provided that Teva, as the first filer, could enter sooner should a second filer gain entry into the market by, for example, proving that Gilead patents were invalid.

168. Gilead's settlement agreements with other generic manufacturers challenging the FTC patents reinforced and compounded the anticompetitive effects of these MFE and MFEP provisions by including promises that Gilead would not authorize further generic entry for a defined period after Teva's initial entry and delaying other generics from entering the market for an additional 6 months after Teva's initial entry.

169. The MFE and MFEP clauses in the Truvada and Atripla settlement agreements were extremely effective at delaying and suppressing generic competition. Each generic manufacturer ultimately agreed to stay out of the market for the period of time that Gilead granted to Teva in the MFEPs, and, in exchange, Teva agreed to delay generic Truvada and Atripla until September 30, 2020, just one year before expiration of the FTC patents.

170. After Gilead and Teva entered into the settlement agreements delaying generic competition for Truvada and Atripla until September 30, 2020, Gilead struck another anticompetitive settlement with Cipla. The settlement agreement with Cipla contained additional anticompetitive provisions, creating another roadblock to generic entry of Truvada and Atripla. Cipla agreed to substantially delay the launch of its standalone generic Emtriva (FTC) product until August 2020 (approximately one month before the agreed-upon date certain for generic entry of Truvada and Atripla) in exchange for undisclosed payments and assurances of exclusivities, despite having received final FDA approval for its generic in July 2018. Further, less than two months after the case settled, Gilead announced it would license Cipla, among others, to sell cheaper versions of new hepatitis C drugs, a potentially very lucrative opportunity for Cipla.[25]

171. As with Viread, a number of second filers lined up behind first-filer Teva challenging Gilead's FTC patents. At the time of Teva's and Gilead's February 2014 settlement, Gilead had already filed patent infringement lawsuits relating to the FTC patents against at least Lupin and Cipla. And with the success of Truvada and Atripla, Teva could anticipate others.

172. Teva and these subsequent filers faced the same economic dynamics as in the case of Viread: the MFEs and MFEPs granted to Teva dissuaded the second filers from continuing to litigate and provided Teva a period of exclusivity. Significantly, at the time of the settlement, Teva had forfeited its 180-day ANDA exclusivity with respect to Truvada, and may have forfeited it with respect to Atripla, by having failed to obtain tentative FDA approval within 30 months of submitting its application. *See* 21 U.S.C. § 355 (j)(5)(D)(i)(I)(aa)(BB).

173. The MFEPs provided that Gilead would not grant a license to any other manufacturer to enter the market with generic Truvada or generic Atripla until at least six months after Teva's agreed entry date. This was of particular importance to Teva because it had either forfeited its eligibility for the 180-day statutory exclusivity period or at the very least was uncertain of that eligibility. The MFEs and MFEPs provided Teva with assurances of 180-day

[25] Manufacturing Chemist, Gilead announces generic licensing agreements with Indian companies (Sept. 16, 2014), https://bit.ly/2lTQvqO.

exclusivity that it was not entitled to by statute or regulation. Teva traded its delay of generic Truvada and Atripla for the guarantee of 180 days of exclusivity.

174. The MFEs further provided that, if any subsequent filer entered the market before Teva's agreed entry date, Teva's permitted entry date would be accelerated correspondingly. No generic manufacturer introduced generic Truvada or Atripla prior to Teva.

175. Gilead succeeded in delaying entry of generic Truvada and Atripla just as it did with respect to Viread. Gilead settled the FTC patent litigations with Cipla and Lupin in 2014; with Mylan in 2015; with Aurobindo and Hetero in 2016; and with Amneal in 2017. Gilead included an MFE in each of those settlement agreements, and all of the manufacturers agreed to delay entering the market until six months after Teva's entry.

176. The reduction in generic competition provided by the MFE and MFEP provisions had enormous value to Teva. At the time of settlement in 2014, annual combined U.S. sales for Atripla and Truvada were approximately $4 billion. As the only generic manufacturer of Truvada and/or Atripla, Teva could expect to sell all of its units at about 90% of the brand price. Entry of multiple generics, however, would swiftly reduce Teva's unit sales and profits per sale. Using the methodology described above in connection with Viread, six months of exclusive sales of those generic products was worth almost $1.5 billion to Teva. Absent the reverse payment to Teva, Teva and subsequent filers would have entered the market sooner than they did. The delay in generic competition protected billions of dollars in Truvada and Atripla branded sales, all at the expense of Plaintiff and other purchasers of those drugs.

177. Moreover, Teva's competitive advantage was not limited to its period of exclusivity. With a guaranteed single-entrant launch date, Teva could ramp up its production and negotiate contracts with its customers to flood the distribution channel with generic products before any second filer entered the market and lock in high prices with long-term sales contracts. The difference between the single-generic price and the multiple-generic price represented a significant cost to purchasers of the drugs.

INTERSTATE COMMERCE

178. Teva's and Gilead's conduct, including the marketing and sale of cART regimen drugs, has had, and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the U.S. During the relevant time period, Teva and Gilead used various devices to effectuate the illegal acts alleged herein, including the U.S. mail, interstate and foreign travel, and interstate and foreign wire commerce.

179. The actions alleged in this Complaint have directly and substantially affected interstate commerce as Teva and Gilead deprived Plaintiff of the benefits of free and open competition in the purchase of cART regimen drugs within the U.S.

MARKET POWER

180. The relevant geographic market is the U.S. and its territories and possessions.

181. At all relevant times, Gilead had market power in the markets for each of Viread, and Truvada and their generic equivalents; and Gilead and BMS had market power over Atripla and its generic equivalents. They had the power to maintain the price of their drugs from these markets at supracompetitive levels without losing sufficient sales to other products.

182. Small but significant, permanent increases in the drugs' prices above competitive levels did not cause a loss of sales sufficient to make the price increases unprofitable. At competitive prices, none of the drugs exhibit significant, positive cross-elasticity of demand with respect to price with any product other than generic versions of the brand drugs.

183. Each of the brand drugs is differentiated from all drug products other than generic versions. Due to its use, varying ability to treat the conditions for which it is prescribed, and its side-effects profile, each of the brand drugs is differentiated from all drug products other than generic versions.

184. Additionally, once the physician and patient find that one of these drugs is well tolerated, and is at a competitive price based on variations of price of 10% or less, the physician and patient are very unlikely to switch to a different HIV drug.

185. The pharmaceutical marketplace is characterized by a "disconnect" between product selection and the payment obligation. State laws prohibit pharmacists from dispensing

many pharmaceutical products, including all of those at issue in this Complaint, to patients without a prescription. The prohibition on dispensing certain products without a prescription creates this disconnect. The patient's doctor chooses which product the patient will buy while the patient (and in most cases his or her insurer) has the obligation to pay for it.

186. Brand manufacturers, including Gilead and BMS, exploit this price disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of costs, are largely insensitive to price differences because they do not pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

187. The relative unimportance of price in the pharmaceutical marketplace reduces the price elasticity of demand or the extent to which unit sales go down when price goes up. This reduced price-elasticity, in turn, gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs is market power. Thus, brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals, including the cART drugs at issue here.

188. At all relevant times, Gilead's product gross margin, which is dominated by cART drugs, has been 74% or higher, and has reached as high as 88%. These margins indicate substantial market power.

189. To the extent that Plaintiff is required to prove market power through circumstantial evidence by first defining a relevant product market the markets relevant here are the markets for Viread, Truvada and Atripla and their respective AB-rated generic equivalents.

190. Purposes and effects of Teva's anticompetitive agreements with Gilead include delaying the entry of generic versions of Viread, Truvada, and Atripla, and impairing competition from generic versions of those products.

191. A relevant market for evaluating that conduct is the market for each of those products and its AB-rated generic equivalent. As demonstrated by the indicia noted above:

a. From October 26, 2001 until at least December 15, 2017, Gilead had market power in the market for Viread and its AB-rated generic equivalents, and during that time had 100% share of that market;

b. from August 2, 2004 to October 2, 2020, Gilead had market power in the market for Truvada and its AB-rated generic equivalents, and during that time had 100% share of that market; and

c. from July 12, 2006 to October 2, 2020, Gilead and BMS had market power in the market for Atripla and its AB-rated generic equivalents, and during that time had 100% share of that market.

MARKET EFFECTS

192. By impeding competition, Teva's anticompetitive conduct with Gilead caused Plaintiff to pay more than it would have paid for branded and generic versions of each relevant drug. Earlier entry of generic versions of each drug would have given purchasers the choice between the branded drug and its generic equivalents, which would have been priced substantially below the brand. This is particularly true with regard to AB-rated generics. Every state's pharmacy substitution laws require or encourage pharmacies to substitute AB-rated generics for branded prescription pharmaceuticals whenever possible. Absent Teva's anticompetitive conduct with Gilead, Plaintiff would have saved hundreds of millions of dollars by purchasing generic versions of each relevant drug earlier. Teva's anticompetitive conduct with Gilead caused Plaintiff to incur overcharges on its purchases of both branded and generic versions of the relevant drugs.

193. Teva's anticompetitive conduct with Gilead created and extended monopolies on each relevant drug. Absent Teva's anticompetitive conduct with Gilead, generic versions of each branded drug would have been sold earlier than they actually were.

194. Teva's anticompetitive conduct with Gilead also harmed Plaintiff by increasing and artificially inflating the prices charged for generic versions of the relevant drugs if and when those generic versions became or will become available. When entering a market, generic manufacturers price their products based on a percentage discount off of the then-prevailing brand

price. Absent Teva's anticompetitive conduct with Gilead, generic versions of the branded drugs would have entered the market sooner and would have been priced at a discount to the lower then-prevailing brand price rather than the higher brand price that prevailed at the time of actual generic entry. Thus, Teva's unlawful conduct with Gilead has caused Plaintiff to pay substantial overcharges on its purchases of each relevant drug.

TOLLING

195. Each time Plaintiff paid an overcharge for the drugs at issue in this Complaint — i.e., each time payment was made at a higher price than would have been paid absent Teva's unlawful conduct with Gilead — a new cause of action accrued for that overcharge.

196. Prior to the filing of this Complaint, Plaintiff was an absent member of the putative classes in *Staley v. Gilead Sciences, Inc.*, Case No. 19-cv-02573 (N.D. Cal.) and *Jacksonville Police Officers & Fire Fighters Health Insurance Trust v. Gilead Sciences, Inc.*, Case No. 20-cv-06522 (N.D. Cal.). Pursuant to the U.S. Supreme Court decision in *American Pipe Construction Co. v. Utah*, 414 U.S. 538 (1974), and its progeny, the class action complaints tolled the applicable statute of limitations as to the claims asserted by Plaintiff. Accordingly, Plaintiff is entitled to recover overcharges (and treble damages) for indirect purchases made starting at least four years prior to the filing of those class actions, i.e., May 14, 2015 and later.

197. Plaintiff is also entitled to recover damages on purchases made from at least as early as November 2014 to the present because Gilead and Teva fraudulently concealed that their settlement agreement contained an unlawful reverse payment, and Plaintiff could not have discovered the existence of Teva's unlawful conduct with Gilead through the exercise of reasonable diligence prior to December 15, 2017, thereby tolling the relevant statute of limitations. Gilead's payment to Teva in the form of a secret No-AG agreement was not discoverable until after Teva launched its generic Viread on December 15, 2017, and Gilead did not launch an authorized generic.

198. Gilead and Teva's scheme was self-concealing, in that, by its nature and design, it was incapable of being detected. In addition, Gilead and Teva actively concealed the terms of their agreement to avoid detection. For example, Gilead and Teva specifically represented to the

court in the underlying patent litigation that their Viread settlement did not contain a No-AG agreement.

199. Because Plaintiff was not aware of Teva's secret, unlawful reverse payment agreement with Gilead, it could not have been aware that Gilead and Teva's other conduct was also part of a monopolistic and anticompetitive scheme and the antitrust violations alleged herein. In particular:

- The No-Generics Restraint agreement between Gilead and BMS had substantially greater anticompetitive effects when used in conjunction with the secret Gilead-Teva generic delay agreement; and
- The MFE and MFEP agreements between Gilead and Teva had substantially greater anticompetitive effects when used in conjunction with the secret Gilead-Teva generic delay agreement.

200. Plaintiff lacked the facts and information necessary to form a good faith basis for believing that legal violations had occurred prior to December 15, 2017.

IMPACT AND CONTINUING INJURY TO PLAINTIFF

201. During the relevant period, Plaintiff purchased substantial quantities of the relevant drugs (and, in some cases, generic versions of the relevant drugs) at supracompetitive prices. As a result of Teva's illegal conduct with Gilead, Plaintiff was compelled to pay, and did pay, artificially inflated prices for those drugs. Those prices were substantially greater than the prices that would have been paid absent the illegal conduct alleged herein, because: (a) the prices of the relevant drugs were artificially inflated by Teva's illegal conduct with Gilead; (b) Plaintiff was deprived of the opportunity to purchase lower-priced generic versions of the relevant drugs, which it would have done had it had the opportunity; and (c) when the generic drugs ultimately became or will become available, the prices of those generic drugs were or will be higher than they would have been absent Teva's unlawful conduct with Gilead.

202. As a direct consequence of Teva's antitrust violations with Gilead, Plaintiff has sustained substantial loss and damage to its business and property in the form of overcharges. The full amount of such damages will be calculated after discovery and upon proof at trial.

203. As a result of Teva's unlawful conduct with Gilead, Plaintiff continues to pay overcharges today, notwithstanding the launch of generic versions of some of the relevant drugs. The commencement of generic competition does not immediately create a competitive environment indistinguishable from the environment that would have existed had generic competition begun much earlier. In fact, it can take considerable time for the process of generic competition to eliminate the effects of prior anticompetitive conduct for several reasons, all of which apply here.

204. First, generic substitution rates do not immediately reach their maximum level when an AB-rated generic drug is launched. While generic substitution by Plaintiff typically reaches a level of 90% in approximately three months, generic substitution rates continue to increase gradually and incrementally after that time and eventually reach 95% or more, at which point they plateau. It may take a year or longer for generic substitution rates to reach this maximum level. Until they do, the actual generic substitution rate will be lower than it would have been had generic entry occurred earlier, and Plaintiff will continue to purchase units of the branded drug that would have been replaced with units of the less-expensive generic drug but for the antitrust violation.

205. Second, generic prices do not immediately drop to the level they would have achieved had generic competition begun earlier. Generic prices typically fall over time even in the absence of additional generic entrants so long as the number of generic manufacturers in the market does not decrease. In this case, generic prices were high, both because of price increases on the relevant drugs and because Teva and other generic entrants did not face competition from other generics upon launch. Even after additional generics entered the markets, generic prices have remained relatively high and continue to remain relatively high today. Had generic competition begun much earlier, as it would have absent Teva's unlawful conduct with Gilead, intergeneric competition would have been underway for a longer period of time and generic prices would have fallen to lower levels than the generic prices Plaintiff is paying today.

206. The fact that generic substitution rates and generic prices can take considerable time to reach the equilibrium levels they would have reached had generic competition begun

earlier means that Plaintiff will continue to pay overcharges on its purchases of the relevant drugs and, where available, generic equivalents for some time to come.

207. Gilead continues to maintain a monopoly in various HIV cART medications, including Descovy, Tybost, Stribild, Genvoya; and, along with others, Complera, Odefsey, Prezcobix, and Symtuza.

208. Teva states that it "is the largest manufacturer of generic drugs in the U.S. and the world." Teva has expressed a "Commitment to HIV" and has stated that "[t]reating HIV is part of our broader mission to nurture healthy communities around the world, through our portfolio and beyond." According to Teva, "[f]or years, Teva has supported patients living with HIV and we continue to do so by delivering quality, cost-effective treatment options to patients."

209. After the settlements described above, Gilead and Teva have engaged in, and settled, subsequent Hatch Waxman patent litigation. For example, on March 26, 2018, Gilead sued Teva for patent infringement in relation to Gilead's Sovaldi hepatitis C drug. Teva answered the complaint on October 1, 2018. On February 11, 2019, the parties submitted an order and stipulation for dismissal, which was entered on February 14, 2019. No generic Sovaldi has yet launched.

210. As Teva has repeatedly entered into multiple unlawful settlements as described above and continues to compete in the HIV cART market, there exists a cognizable danger of recurrent violation and significant threat of injury from this contemporary violation that Teva will enter into another unlawful patent settlement agreement.

CLAIMS FOR RELIEF

COUNT I:
Conspiracy to Monopolize /Restrain Trade in Violation of Sections 1 and 2 of the Sherman Antitrust Act (15 U.S.C. §§ 1, 2)

211. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

212. At all relevant times, Gilead has possessed substantial market power in the relevant cART markets. More than 80% of patients starting an HIV regimen in the U.S., and

more than 80% of patients continuing on a HIV regimen, take one of Gilead's products every day. Gilead has the market shares alleged in detail above and possesses the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant cART markets.

213. That market power is coupled with strong regulatory and contractual barriers to entry into the cART market.

214. As stated more fully above, Teva enlisted Gilead in a conspiracy to monopolize, and willfully obtained and maintained Gilead's monopoly power in the relevant cART markets including by entering into and abiding by the illegal patent settlement agreements.

215. Teva consciously committed to the monopolization scheme when it entered into the patent settlement agreements protecting Gilead's drugs from generic competition, entered into No-AG, MFE, and MFEP provisions to protect Gilead's drugs from generic competition, and abided by those agreements.

216. Teva knew that Gilead was seeking to obtain and maintain monopoly power in the relevant cART markets. It knew that: (a) tenofovir was a critical backbone of cART therapies and TDF would dominate the cART market; (b) its settlements with Gilead would delay generic competition, and (c) its settlements with Gilead would deter other potential generic competitors from seeking to enter the market.

217. By the time it agreed to the 2013 patent settlement agreement regarding TDF, Teva knew that Gilead and/or BMS had the only Viread, Truvada, and Atripla drugs on the market and none of their respective AB-rated generic equivalents were available. As of that date, Teva also knew from Gilead's public SEC filings that Gilead had entered into a No-Generics Restraint with BMS protecting Gilead's drugs from competition. Teva therefore knew that its unlawful agreement substantially contributed to Gilead's unlawful maintenance of a monopoly in the markets for relevant cART drugs.

218. By the time it agreed to the 2014 patent settlement agreement regarding FTC, Teva knew that Gilead and/or BMS had the only Truvada and Atripla drugs on the market and none of their respective AB-rated generic equivalents were available. As of that date, Teva also knew from Gilead's public SEC filings that Gilead had entered into a No-Generics Restraint with BMS

protecting Gilead's drugs from competition. Teva therefore knew that its unlawful agreement substantially contributed to Gilead's unlawful maintenance of a monopoly in the markets for relevant cART drugs.

219. Teva participated in the conspiracy to monopolize with Gilead because Teva benefitted directly from it, including from: (a) the generic exclusivity it enjoyed upon launching AB-rated generic equivalents of Viread, Truvada, and Atripla; (b) the lack of competition from a Gilead AG competitor; (c) the opportunities it had to lock in supply agreements as the first generic entrant; (d) the MFE and MFEP clauses that ensured Teva would be afforded the earliest, most favorable generic launch; and (e) the supracompetitive prices Teva could charge on its generic equivalents.

220. To the extent Teva is permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for the companies' conduct comprising the anticompetitive scheme that outweighs its harmful effects. Even if there were some conceivable such justification that Teva were permitted to assert, the scheme is and was broader and more anticompetitive than necessary to achieve such a purpose.

221. As Gilead and Teva have repeated their unlawful conduct through multiple patent settlement agreements as alleged herein, there is a significant threat of injury to Plaintiff that Teva will continue to engage in this contemporary violation that is likely to recur. There exists a cognizable danger of recurrent violation as brand manufacturers such as Gilead continue to innovate and compete in the growing HIV cART market and Teva continues to seek approval to bring the corresponding generics to the same market.

222. Plaintiff has been injured, and unless Teva's unlawful conduct is enjoined pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, will continue to be injured, in its business and property as a result of Teva's continuing conspiracy with Gilead and the significant threat of injury from future antitrust violations in violation of Sections 1 and 2 of the Sherman Act.

COUNT II:
Conspiracy to Restrain Trade / Restraint of Trade in Violation of California's Cartwright Act

223. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

224. Teva violated California's Cartwright Act by entering into and adhering to a contract, combination, or conspiracy with Gilead in unreasonable restraint of trade, namely: (a) Gilead's agreement to make a reverse payment to Teva in exchange for Teva's agreement to delay its launch of generic Viread until December 15, 2017; and (b) Gilead's agreement to make a reverse payment to Teva in exchange for Teva's agreement to delay its launch of generic Truvada and Atripla until September 30, 2020.

225. At all relevant times, Gilead had substantial market power with respect to sales of Truvada and its AB-rated generic equivalents in the U.S.

226. As alleged in detail above, on or about February 19, 2013, Gilead and Teva entered into a reverse-payment agreement, under which Gilead agreed to pay, and Teva agreed to receive, substantial consideration in exchange for Teva's agreement to delay bringing a generic version of Viread to the market. The purposes and effects of that agreement were to: (a) prevent the sale of a generic version of Viread in the U.S., thereby lengthening the period of time when Viread was protected from generic competition; (b) allow Teva to earn supracompetitve profits on generic Viread due to the absence of competition from other generic manufacturers; (c) delay the date when other generic manufacturers would enter the market; and (d) maintain prices for Viread and its AB-rated generic equivalents at supracompetitive levels. This reverse payment from Gilead to Teva exceeded Gilead's anticipated litigation costs to continue pursuing the patent litigation, and was worth substantially more than what Teva could have earned if it had prevailed in the patent litigation and come to market with a generic Viread in competition with Gilead's AG.

227. Additionally, in or about February 2014, Gilead and Teva entered into another reverse payment agreement, a continuing illegal contract, combination, and restraint of trade under which Gilead agreed to pay, and Teva agreed to receive, substantial consideration in

exchange for Teva's agreement to delay bringing its generic versions of Truvada and Atripla to market. The purposes and effects of the reverse payment were to: (a) delay generic entry of Truvada and Atripla in order to lengthen the period in which Gilead would earn supracompetitive profits on sales of Truvada and Atripla; (b) allow Teva to earn supracompetitive profits on generic Truvada and Atripla due to the absence of competition from other generic manufacturers; (c) delay the date that other generic manufacturers would enter that market; and (d) raise and maintain the prices that Plaintiff would pay for Truvada, Atripla, and their AB-rated equivalents at supracompetitive levels.

228. By entering into the unlawful agreements, Teva unlawfully conspired with Gilead to and did restrain trade, thereby violating California's Cartwright Act.

229. Teva's unlawful acts with Gilead had, and continue to have, a substantial and foreseeable effect on California commerce by artificially raising and fixing prices for the drugs at issue.

230. Teva's unlawful activities with Gilead, as described in this Complaint, also affected both intrastate commerce and interstate commerce flowing into or out from California and had direct, substantial, and reasonably foreseeable effects upon trade and commerce in California.

231. During the relevant period, through Gilead, Teva, or the regional and national distributors and retailers they have engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold each year in California. Moreover, Gilead sells all of its HIV cART drugs from its headquarters in California.

232. There is and was no legitimate, procompetitive justification for the anticompetitive restraint. Even if there were some conceivable and cognizable justification, the reverse payments were not necessary to achieve such a purpose, and, in any event, such procompetitive effects would be outweighed by the restraint's anticompetitive effects on purchasers, competition, and consumers.

233. As a direct and proximate result of Teva's violation of the Cartwright Act, Plaintiff has been harmed by paying artificially inflated, supracompetitive prices for relevant HIV cART

drugs dispensed to its members and suffered damages in an amount to be proven at trial. Plaintiff's injury consists of having paid higher prices for Viread, Truvada, Atripla, and their generic equivalents, and continuing to pay higher prices than it would have paid in the absence of the antitrust violation. Such injury is of the type the antitrust laws were designed to prevent, and flows from that which makes Teva's conduct with Gilead unlawful.

COUNT III:
Conspiracy to Restrain Trade / Restraint of Trade in Violation of Various State Antitrust Laws

234. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

235. This claim for relief is pleaded in the alternative to the Second Count, in the event it is determined that all of Plaintiff's claims for relief related to its payments and reimbursements for cART drugs are not governed by California law.

236. Teva violated various state antitrust laws by entering into and adhering to a contract, combination, or conspiracy with Gilead in unreasonable restraint of trade, namely: (a) Gilead's agreement to make a reverse payment to Teva in exchange for Teva's agreement to delay its launch of generic Viread until December 15, 2017; and (b) Gilead's agreement to make a reverse payment to Teva in exchange for Teva's agreement to delay its launch of generic Truvada and Atripla until September 30, 2020.

237. At all relevant times, Gilead had substantial market power with respect to sales of Truvada and its AB-rated generic equivalents in the U.S.

238. As alleged in detail above, on or about February 19, 2013, Gilead and Teva entered into a reverse-payment agreement, under which Gilead agreed to pay, and Teva agreed to receive, substantial consideration in exchange for Teva's agreement to delay bringing a generic version of Viread to the market. The purposes and effects of that agreement were to: (a) prevent the sale of a generic version of Viread in the U.S., thereby lengthening the period of time when Viread was protected from generic competition; (b) allow Teva to earn supracompetitve profits on generic Viread due to the absence of competition from other generic manufacturers; (c) delay the date when other generic manufacturers would enter the market; and (d) maintain prices for Viread

and its AB-rated generic equivalents at supracompetitive levels. This reverse payment from Gilead to Teva exceeded Gilead's anticipated litigation costs to continue pursuing the patent litigation, and was worth substantially more than what Teva could have earned if it had prevailed in the patent litigation and come to market with a generic Viread in competition with Gilead's AG.

239. Additionally, in or about February 2014, Gilead and Teva entered into another reverse payment agreement, a continuing illegal contract, combination, and restraint of trade under which Gilead agreed to pay, and Teva agreed to receive, substantial consideration in exchange for Teva's agreement to delay bringing its generic versions of Truvada and Atripla to market. The purposes and effects of the reverse payment were to: (a) delay generic entry of Truvada and Atripla in order to lengthen the period in which Gilead would earn supracompetitive profits on sales of Truvada and Atripla; (b) allow Teva to earn supracompetitive profits on generic Truvada and Atripla due to the absence of competition from other generic manufacturers; (c) delay the date that other generic manufacturers would enter that market; and (d) raise and maintain the prices that Plaintiff would pay for Truvada, Atripla and their AB-rated equivalents at supracompetitive levels.

240. By entering into the unlawful agreements, Teva unlawfully conspired with Gilead to and did restrain trade, thereby violating antitrust laws in the following states:

a. Ala. Code §§ 8-10-3, *et seq.*, with respect to purchases of relevant HIV cART drugs in Alabama;

b. Ariz. Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of relevant HIV cART drugs in Arizona;

c. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and California common law, with respect to purchases of relevant HIV cART drugs in California;

d. Conn. Gen. Stat. §§ 35-26, *et seq.*, with respect to purchases of relevant HIV cART drugs in Connecticut;

e. D.C. Code §§ 28-4502, *et seq.*, with respect to purchases of relevant HIV cART drugs in the District of Columbia;

f. Haw. Rev. Stat. §§ 480-2, *et seq.*, with respect to purchases of relevant HIV cART drugs in Hawaii;

g. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of relevant HIV cART drugs in Illinois;

h. Iowa Code §§ 553.4, *et seq.*, with respect to purchases of relevant HIV cART drugs in Iowa;

i. Kan. Stat. Ann. §§ 50-161(b), *et seq.*, with respect to purchases of relevant HIV cART drugs in Kansas;

j. Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, with respect to purchases of relevant HIV cART drugs in Maine;

k. Md. Code Ann., Com. Law §§ 11-201, *et seq.*, with respect to purchases of relevant HIV cART drugs in Maryland;

l. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of relevant HIV cART drugs in Michigan;

m. Minn. Stat. §§ 325D.51, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases of relevant HIV cART drugs in Minnesota;

n. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of relevant HIV cART drugs in Mississippi;

o. Mont. Code Ann. §§ 30-14-201, *et seq.*, with respect to purchases of relevant HIV cART drugs in Montana;

p. Neb. Rev. Stat. §§ 59-801, *et seq.*, with respect to purchases of relevant HIV cART drugs in Nebraska;

q. Nev. Rev. Stat. §§ 598A.060, *et seq.*, with respect to purchases of relevant HIV cART drugs in Nevada;

r. N.H. Rev. Stat. Ann. §§ 356:2, *et seq.*, with respect to purchases of relevant HIV cART drugs in New Hampshire;

s. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of relevant HIV cART drugs in New Mexico;

t. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of relevant HIV cART drugs in New York;

u. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of relevant HIV cART drugs in North Carolina;

v. N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of relevant HIV cART drugs in North Dakota;

w. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of relevant HIV cART drugs in Oregon;

x. P.R. Laws Ann. tit. 10 §§ 257, *et seq.*, with respect to purchases of relevant HIV cART drugs in Puerto Rico;

y. R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases of relevant HIV cART drugs in Rhode Island;

z. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchases of relevant HIV cART drugs in South Dakota;

aa. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of relevant HIV cART drugs in Tennessee, in that the actions and transactions alleged herein substantially affected Tennessee trade or commerce;

bb. Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*, with respect to purchases of relevant HIV cART drugs in Vermont;

cc. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of relevant HIV cART drugs in West Virginia; and

dd. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of relevant HIV cART drugs in Wisconsin.

241. Teva's unlawful acts with Gilead had, and continue to have, a substantial and foreseeable effect on the commerce of each above state and territory by artificially raising and fixing prices for the drugs at issue paid for and/or dispensed in each state or territory.

242. Teva's unlawful activities with Gilead, as described in this Complaint, also affected both intrastate commerce and interstate commerce flowing into or out from each of the above states and territories, and had direct, substantial, and reasonably foreseeable effects upon trade and commerce in each respective state or territory.

243. During the relevant period, through Gilead, Teva, or the regional and national distributors and retailers they have engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold in each of the above states and territories every year.

244. There is and was no legitimate, procompetitive justification for the anticompetitive restraint. Even if there were some conceivable and cognizable justification, the reverse payments were not necessary to achieve such a purpose, and, in any event, such procompetitive effects would be outweighed by the restraint's anticompetitive effects on purchasers, competition, and consumers.

245. As a direct and proximate result of Teva's violation of the various states' antitrust laws, Plaintiff has been harmed by paying artificially inflated, supracompetitive prices for relevant HIV cART drugs dispensed to its members in these states and territories and suffered damages in an amount to be proven at trial. Plaintiff's injury consists of having paid higher prices for Viread, Truvada, Atripla and their generic equivalents, and continuing to pay higher prices than it would have paid in the absence of the antitrust violation. Such injury is of the type the antitrust laws were designed to prevent, and flows from that which makes Teva's conduct with Gilead unlawful.

COUNT IV:
Violation of Various State Unfair and Deceptive Trade Practices and Consumer Protection

246. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

247. By engaging in the foregoing anticompetitive conduct alleged above, Teva has violated the unfair and deceptive trade practices and consumer protection statutes of all the states and territories, including but not limited to all of the following:

a. Ariz. Code §§ 44-1522, *et seq.*, with respect to purchases of relevant HIV cART drugs in Arizona;

b. Ark. Code Ann. §§ 4-88-101, *et seq.*, with respect to purchases of relevant HIV cART drugs in Arkansas;

c. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases of relevant HIV cART drugs in California;

d. Colo. Rev. Stat §§ 6-1-105, *et seq.*, with respect to purchases of relevant HIV cART drugs in Colorado;

e. D.C. Code §§ 28-3901, *et seq.*, with respect to the purchases of relevant HIV cART drugs in the District of Columbia;

f. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of relevant HIV cART drugs in Florida;

g. Idaho Code §§ 48-601, *et seq.*, with respect to purchases of relevant HIV cART drugs in Idaho;

h. 815 Ill. Comp. Stat. 505/1, *et seq.*, with respect to purchases of relevant HIV cART drugs in Illinois;

i. Ind. Code §§ 24-5-0.5-1, *et seq.*, with respect to purchases of relevant HIV cART drugs in Indiana;

j. La. Stat. Ann. §§ 51:1401, *et seq.*, with respect to purchases of relevant HIV cART drugs in Louisiana;

k. Me. Stat. tit. 5 §§ 207, *et seq.*, with respect to purchases of relevant HIV cART drugs in Maine;

l. Mass. Gen. Laws ch. 93A § 11, with respect to purchases of relevant HIV cART drugs in Massachusetts;

m. Mich. Comp. Laws §§ 445.901, *et seq.*, with respect to purchases of relevant HIV cART drugs in Michigan;

n. Minn. Stat. §§ 325D.43, *et seq.*, Minn. Stat. §§ 325F.69, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases of relevant HIV cART drugs in Minnesota;

o. Miss. Code. Ann. §§ 75-24-1, *et seq.*, with respect to purchases of relevant HIV cART drugs in Mississippi;

p. Mo. Rev. Stat. §§ 407.010, *et seq.*, with respect to purchases of relevant HIV cART drugs in Missouri;

q. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of relevant HIV cART drugs in Nebraska;

r. Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases of relevant HIV cART drugs in Nevada;

s. N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases of relevant HIV cART drugs in New Hampshire;

t. N.M. Stat. Ann. §§ 57-12-1, *et seq.*, with respect to purchases of relevant HIV cART drugs in New Mexico;

u. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases of relevant HIV cART drugs in New York;

v. N.C. Gen. Stat. §§ 75-1.1, *et seq.*, with respect to purchases of relevant HIV cART drugs in North Carolina;

w. N.D. Cent. Code §§ 51-15-01, *et seq.*, with respect to purchases of relevant HIV cART drugs in North Dakota;

x. 73 Pa. Cons. Stat. §§ 201-1, *et seq.*, with respect to purchases of relevant HIV cART drugs in Pennsylvania;

y. S.C. Code Ann. §§ 39-5-10, *et seq.*, for purchases of relevant HIV cART drugs in South Carolina;

z. S.D. Codified Laws §§ 37-24-1, *et seq.*, with respect to purchases of relevant HIV cART drugs in South Dakota;

aa. Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*, with respect to purchases of relevant HIV cART drugs in Vermont;

bb. Va. Code Ann. §§ 59.1-196, *et seq.*, with respect to purchases of relevant HIV cART drugs in Virginia;

cc. W.Va. Code §§ 46A-6-101, *et seq.*, with respect to purchases of relevant HIV cART drugs in West Virginia;

dd. Wis. Stat. § 100.18; Wis. Stat. §§ 100.20, *et seq.*, with respect to purchases of relevant HIV cART drugs in Wisconsin; and

ee. Wyo. Stat. Ann. §§ 40-12-101, *et seq.*, with respect to purchases of relevant HIV cART drugs in Wyoming.

248. Teva's unlawful acts with Gilead had, and continue to have, a substantial and foreseeable effect on the commerce of each above state and territory by artificially raising and fixing prices for the drugs at issue paid for and/or dispensed in each state or territory.

249. Teva's unlawful activities with Gilead, as described in this Complaint, affected both intrastate commerce and interstate commerce flowing into or out from each of the above states and territories, and had direct, substantial, and reasonably foreseeable effects upon trade and commerce in each respective state or territory.

250. During the relevant period, through Teva, Gilead, or the regional and national distributors and retailers that they have engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold in each of the above states and territories every year.

251. As a direct and proximate result of Teva's violation of each of the foregoing laws, Plaintiff has been harmed by paying artificially inflated, supracompetitive prices for the drugs

dispensed to its members throughout the U.S. and suffered damages in an amount to be proven at trial.

COUNT V:
Unjust Enrichment

252. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

253. Teva has benefited from artificially high prices in the sale of the relevant HIV cART drugs resulting from the unlawful and inequitable acts alleged throughout this Complaint.

254. Teva's financial benefit resulting from their unlawful and inequitable acts are traceable to overpayments for the relevant HIV cART drugs made by Plaintiff.

255. Plaintiff has conferred upon Teva an economic benefit, profits from unlawful overcharges, to the economic detriment of Plaintiff.

256. It would be futile for Plaintiff to seek a remedy from any party with whom it has privity of contract for its indirect purchases of the relevant HIV cART drugs.

257. It would be futile for Plaintiff to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it purchased relevant HIV cART drugs, as any intermediary is not liable and would not compensate Plaintiff for the impact of Teva's unlawful conduct with Gilead.

258. The economic benefit of overcharges derived by Teva through charging supracompetitive and artificially inflated prices for relevant HIV cART drugs is a direct and proximate result of Teva's unlawful conduct with Gilead.

259. The economic benefits derived by Teva rightfully belongs to Plaintiff, as it paid anticompetitive and monopolistic prices during the relevant period, benefiting Teva.

260. It would be inequitable under unjust enrichment principles under the law of the District of Columbia and the laws of all states and territories in the U.S., except Ohio and Indiana, for Teva to be permitted to retain any of the overcharges for the relevant HIV cART drugs derived from Teva's unfair and unconscionable methods, acts, and trade practices with Gilead alleged in this Complaint.

261. Teva is aware of and appreciates the benefits bestowed upon them by Plaintiff.

262. Teva should be compelled to disgorge in a common fund for the benefit of Plaintiff all unlawful or inequitable proceeds it received.

263. A constructive trust should be imposed upon all unlawful or inequitable sums received by Teva that are traceable to Plaintiff.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff respectfully requests entry of judgment against Defendant and the following relief:

A. A declaration that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act;

B. Permanent injunctive relief enjoining Defendant from continuing its illegal conduct and requiring it to take affirmative steps to dissipate the continuing effects of its prior conduct;

C. An award of Plaintiff's actual, consequential, and compensatory damages, trebled, and/or other damages, in an amount to be proven at trial, including pre- and post-judgment interest at statutory rates;

D. Equitable relief in the nature of disgorgement, restitution, and/or the creation of a constructive trust to remedy Defendant's violations of various state unfair and deceptive trade practices, consumer protection, and unjust enrichment laws;

E. An award of Plaintiff's costs of suit, including reasonable attorneys' fees as provided by law; and

F. Such other and further relief as the Court deems just and proper.

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JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Dated: December 14, 2021

Respectfully submitted,

BERRY SILBERBERG STOKES PC

/s/ Joshua C. Stokes

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